

*Research Article*

## Vaginal Misoprostol versus Bilateral Uterine Artery Ligation versus pericervical mechanical tourniquet in Decreasing Blood Loss in Trans-Abdominal Myomectomy: A Randomized Controlled Trial

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### Abstracts

**Introduction:** Uterine leiomyomas are tumors of the myometrium that have a prevalence as high as 70% to 80% at the age of 50. **Aim of the Work:** The aim of the current study is to evaluate the effectiveness of preoperative vaginal misoprostol vs bilateral uterine artery ligation vs pericervical mechanical tourniquet compared to each others and to a control group in decreasing blood loss in trans-abdominal myomectomy.

**Patients and Methods. Study Design: Randomized controlled interventional clinical trial.** The study was being conducted in gynaecology department; Minia University Maternity Hospital in the period between September 2018- to May 2019 after approval of the MEDICAL Ethical Research Committee.

**Results:** This study included a total of 48 patients who were randomly divided into 4 groups (12 patients each) as follow: **Group (1) Vaginal Misoprostol:** Patients were given 200 microgram misoprostol vaginally (Cytotec<sup>®</sup> TAB 200 microgram , Pfizer Factory) preoperatively. **Group (2) uterine artery ligation:** Patients in whom uterine artery ligation was done. **Group (3) pericervical tourniquet:** Patients in whom pericervical mechanical tourniquet using Foley catheter was applied around both uterine vessels. **Group (4) Control:** Trans-abdominal myomectomy group using the classic technique; no intervention. **Discussion:** Uterine leiomyomas are tumors of the myometrium that have prevalence as high as 70% to 80% at the age of 50, the etiology and prevalence seem to vary with a number of factors including age, race, and possibly geographic location. Prevalence in the United States is almost 40% in white patients and more than 60% in women of African descent in the same age group (Parker, 2007). **Recommendations:** Preoperative vaginal misoprostol is an effective practical tool in decreasing blood loss in transabdominal myomectomy.

**Keywords:** Misoprostol, Uterine Artery Ligation, pericervical mechanical tourniquet, Trans-Abdominal Myomectomy.

### Introduction

Uterine leiomyomas are tumors of the myometrium that have a prevalence as high as 70% to 80% at the age of 50<sup>(1)</sup>, the etiology and prevalence seem to vary with a number of factors including age, race, and possibly geographic location. Prevalence in the United States is almost 40% in white patients and more than 60% in women of African descent in the same age group<sup>(2)</sup>.

Leiomyomas are listed as the diagnosis for about 39% of the approximately 600,000 hysterectomies performed each year in the United States<sup>(3)</sup>.

These benign tumors, are usually asymptomatic, and may be only detectable through ultrasound examination, or associated with a

number of clinical issues including abnormal uterine bleeding (AUB) especially heavy menstrual bleeding (HMB), infertility, recurrent pregnancy loss, and complaints related to the impact of the enlarged uterus on adjacent structures in the pelvis, which are often referred to as “bulk” symptoms. It is generally perceived that the symptoms of HMB, infertility, and recurrent pregnancy loss largely occur as a result of lesions that distort the endometrial cavity that are therefore adjacent to the endometrium and consequently referred to as submucous leiomyomas<sup>(4)</sup>.

Treatment options for leiomyoma vary; treatment strategies are typically individualized based on the severity of the symptoms, the size and location of the leiomyoma lesions, the patient’s age and their chronological proximity

to menopause, and the patient's desire for future fertility. The usual goal of therapy is the relief of the symptoms. The treatment options range from the use of acupuncture (ancient Chinese method) to the total removal of the uterus and its myoma contents (hysterectomy)<sup>(5)</sup>.

### **Aim of the Work**

The aim of the current study is to evaluate the effectiveness of preoperative vaginal misoprostol vs bilateral uterine artery ligation vs pericervical mechanical tourniquet compared to each others and to a control group in decreasing blood loss in trans-abdominal myomectomy.

### **Patients and Methods**

#### **Study Design:**

#### **Randomized controlled interventional clinical trial.**

The study was being conducted in gynaecology department; Minia University Maternity Hospital in the period between September 2018- to May 2019 after approval of the MEDICAL Ethical Research Committee.

Forty eight patients with symptomatic fibroids diagnosed by clinical examination and ultrasound scan (+/- MRI and /or CT scan whenever indicated) and scheduled for surgery were included in the study. Patients were eligible for and requesting myomectomy. Informed consent was being obtained from each participant.

**Inclusion criteria were included** patients in the age group between 20-40 years with symptomatic fibroids complaining from abnormal uterine bleeding (menorrhagia and/or metrorrhagia) and/or pain (dull aching lower abdominal pain and/or dysmenorrhea) and/ or pressure symptoms (dysparunia, dysuria, dyschezia and/or backache) and/or progressive abdominal enlargement (abdominal swelling). Patients myomas were subserous or intramural as diagnosed by ultrasound +/- other imaging techniques, whereas the maximum diameter of the largest fibroid is >4cm and up to 10cm. with a uterine size +/- 14 wks with a total number of ≤ 5.

#### **Exclusion criteria were the following;**

Obesity (BMI >30 kg/m<sup>2</sup>). Or positive pregnancy test; Patients with history of a bleeding disorder, concurrent anticoagulant

therapy, those who received pre-operative hormonal therapy (such as a GnRH analogue).

Or patients known to be allergic to prostaglandin preparations or those with Cardiac, pulmonary, endocrine or hematological disease (including anemia; hemoglobin level <10 gm/dl) will be excluded from the study. Also, patients diagnosed as having submucous, cervical, supracervical, broad ligamentary and pedunculated myomas. Further more patients presented by or with suspected pre or malignant gynecological disease or those with any associated pelvic pathology other than uterine myomas. Or patients with contraindication to general anaesthesia were excluded from the study

In this randomized double blind (PATIENTS AND SURGICAL TEAM) controlled study patients (48) were randomly divided into 4 groups; (12 patients each) three study groups and a control group using sealed sequentially numbered opaque envelopes containing computer generated random number. Randomization was being immediately before surgery and neither the patient nor the surgical team was being informed of their assignment.

#### **These groups are;**

**Group (1) (study group I):** Patients given 200 microgram misoprostol vaginally within two hours (Cytotec<sup>®</sup> TAB 200 microgram, Pfizer Factory) preoperatively.

**Group (2) (study group II):** Patients in whom uterine artery ligation was done.

**Group (3) (study group III):** Patients in whom pericervical mechanical tourniquet using Foley catheter was applied around both uterine vessels

**Group (4) (control group IV):** Transabdominal myomectomy group using the classic technique; no intervention

#### **Surgical technique**

Preoperative evaluation, preparations and admission was done according to the standard protocols. Anaesthesia techniques was according to the standard protocol for general anaesthesia. Side effects if any recorded. Abdominal myomectomy was performed by the usual standard surgical technique through a transverse suprapubic incision (Mukhopadhyaya et al., 2008). All myomectomies were performed by the same surgical team and they were blinded to the randomization.

### Blood loss estimates

Pre and post operative blood haemoglobin was recorded. Any intraoperative and/or post-operative transfusion (s) was be recorded.

The total volume of intraoperative blood loss was estimated by measuring the amount of blood accumulated in the suction equipment bottle and the amount of blood in the surgical gauze using the alkaline haematin technique. Patients were discharged in the 3<sup>rd</sup> day unless otherwise indicated. OPD appointment was in the 7<sup>th</sup> postoperative day and on the 3<sup>rd</sup> and 6<sup>th</sup> week postoperative, respectively unless otherwise indicated.

### Outcome measures

The primary outcome measure the efficacy of each intervention in decreasing of the blood loss as calculated by the above mentioned technique. Secondary outcome measurers was change of haemoglobin level haematocrit level after operation ,operative time , hospital stay

and intra operative and post operative complications were recorded.

### Results

This study included a total of 48 patients who were randomly divided into 4 groups (12 patients each) as follow:

- **Group (1) Vaginal Misoprostol:** Patients were given 200 microgram misoprostol vaginally (Cytotec<sup>®</sup> TAB 200 microgram, Pfizer Factory) pre-operatively.
- **Group (2) uterine artery ligation:** Patients in whom uterine artery ligation was done.
- **Group (3) pericervical tourniquet:** Patients in whom pericervical mechanical tourniquet using Foley catheter was applied around both uterine vessels.
- **Group (4) Control:** Trans-abdominal myomectomy group using the classic technique; no intervention.

**Table (1): Baseline characteristics of study population.**

Table		Descriptive (n=48)
Age (year) $\bar{x} \pm SD$ (range)		31.7 $\pm$ 3.3 (25-38)
BMI (kg/m <sup>2</sup> ) $\bar{x} \pm SD$ (range)		26.9 $\pm$ 2.11 (22.9-31.2)
Gravidity No Percent	No	20 (41.7%)
	Yes	28 (58.3%)
Use of hormonal contracept.	No	31 (64.6%)
	Yes	17 (35.4%)
Myoma site	Interstitial	29 (60.4%)
	Subserous	12 (25.0%)
	Mixed	7 (14.6%)

Quantitative data were presented as mean  $\pm$  SD (range).

Qualitative data were presented as No. (%).

The mean age of study group was 31.7  $\pm$  3.3 while BMI was 26.9  $\pm$  2.11. The Gravidity was 20 in nulli and 28 in Multi. Patients whom used hormonal contraception were 17 while not used were 31. The mean of Inersitial type of myoma was 29 but in Suberus type was 12 while 7 in mixed myoma.

### Discussion

Uterine leiomyomas are tumors of the myometrium that have prevalence as high as 70% to 80% at the age of 50, the etiology and prevalence seem to vary with a number of factors including age, race, and possibly geographic location. Prevalence in the United States is almost 40% in white patients and more

than 60% in women of African descent in the same age group<sup>(6)</sup>

These benign tumors, are usually asymptomatic, and may be only detectable through ultrasound examination, or associated with a number of clinical issues including abnormal uterine bleeding (AUB) especially heavy menstrual bleeding (HMB), infertility, recurrent pregnancy loss, and complaints related to the impact of the enlarged uterus on adjacent structures in the pelvis. It is generally perceived that the symptoms of HMB, infertility, and recurrent pregnancy loss largely occur as a result of lesions that distort the endometrial cavity that are therefore adjacent to the endometrium and consequently referred to as submucous leiomyomas<sup>(7)</sup>.

Treatment options for leiomyoma vary; treatment strategies are typically individualized based on the severity of the symptoms, the size and location of the leiomyoma lesions, the patient's age and their chronological proximity to menopause, and the patient's desire for future fertility. The usual goal of therapy is the relief of the symptoms. The treatment options range from the use of acupuncture (ancient Chinese method) to the total removal of the uterus and its myoma contents (hysterectomy)<sup>(8)</sup>

### Conclusion

A single pre-operative dose of 200 micrograms of vaginal misoprostol or bilateral uterine artery ligation or pericervical mechanical tourniquet are effective methods in decreasing blood loss in transabdominal myomectomy compared standred myomectomy technique. Misoprostol is a simple, cheap, fast, available and applicable tool that can be administered even an hour preoperativel, bilateral uterine artery ligation is also effective in decreasing blood loss intraoperatively, but needs skilled operative technique.

Therefore, the choice between application of any technique is left to the surgeon's surgical capabilities and preference.

### Recommendations

- 1) Preoperative vaginal misoprostol is an effective practical tool in decreasing blood loss in transabdominal myomectomy. Investigation of misoprostol use in larger population groups and with different dosages

and administration routes, and bilateral uterine artery ligation and pericervical tourniquet are effective methods in decreasing blood loss in transabdominal myomectomy.

- 2) Future researches with addition of comparison between vaginal and other routes for misoprostol usage in decreasing blood loss in transabdominal myomectomy
- 3) Repeat the present study in other hospitals in different parts of Egypt to emphasize our conclusion.

### References

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