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OROGINAL ARTICLE

Peri-cervical Uterine Artery Tourniquet Versus trans-rectal Misoprostol for reducing intraoperative blood loss during transabdominal myomectomy: A prospective randomized controlled clinical trial

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ABSTRACT

Background: Sever intra-operative bleeding is often a problem in transabdominal myomectomy indicating blood transfusion in up to 20% of women. **Aim of work**: to compare the effectiveness of Pericervical uterine artery tourniquet versus pre-operative transrectal misoprostol in decreasing blood loss during transabdominal myomectomy. **Patients and Methods:** this Prospective randomized controlled interventional clinical trial on 72 women with symptomatic uterine leiomyomas and fulfilling the inclusion criteria of the study were admitted to gynecology department, zagazig university hospital during period from (March 2017 –March 2019) for abdominal myomectomy. Patients were randomly divided into two groups Group A (36 participants) in which the patients underwent Pericervical mechanical tourniquet where an incision about 1 cm was made in a clear space at the level of internal os bilaterally then a Foley's catheter was applied as tourniquet through the incisions. Group B (36 participants) in which the patients received 40 microgram misoprostol transrectal 1 hour before the surgery. Intraoperative blood loss, the need for blood transfusion, the need for conversion from myomectomy to hysterectomy, Total operative time, Difference between pre and post-operative hemoglobin and hematocrit levels and Duration of hospital stay were compared between two groups. **Results:** the difference in the intraoperative blood loss between both groups was 24.5 ml with more blood loss in misoprostol group, yet there was no statistically significant difference between group A and group B regarding estimated intraoperative blood loss (469.4±104.5, vs. 493±125.2ml respectively). There was no statistically significant difference between both groups regarding the need for blood transfusion. Regarding operative time no statistically significant difference between both groups. There was statistically significant difference between both groups regarding postoperative complications (blood transfusion and fever) p=0.013. There was no statistically significant difference between both groups regarding hospital stay and drain collection. **Conclusions:** Pericervical uterine artery tourniquet is more effective method in reducing both intraoperative and postoperative blood loss, and shortening of operative time during transabdominal myomectomy.

Keywords: blood loss, fibroid, myomectomy, uterine artery tourniquet, rectal misoprostol.

INTRODUCTION

Uterine fibroid are benign, hormone-sensitive tumors of the smooth muscles: the incidence in women of child-bearing are reported to be as high as 40%, depending on age. Fibroids are considered the most common benign uterine tumors in women of reproductive age. Associated symptoms include dysmenorrheal, spotting and hypermenorrhea leading to anemia, lower abdominal pain, pressure on adjacent organs and disorders of micturition and defecation. Submucosal and intramural fibroids which distort the endometrial cavity are considered to impair fertility [(1)].

Treatment options for leiomyoma; treatment strategies are typically individualized

based on the severity of the symptoms, the size and location of the leiomyoma lesions, the patient's age, 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) [(2)].

The presence of leiomyomas in the uterus distorts normal vascular architecture, thus, the arcuate arteries may run in any axis, rather than transversely, therefore, either vertical or transverse incisions during myomectomy may transect these vessels and increase blood loss during the procedure [(3)].

Interventions on uterine arteries: such as uterine artery embolization [(4)], Pericervical mechanical tourniquet, vasopressin (natural or synthetic), a vasoconstrictive solution of bupivacaine plus epinephrine and bilateral uterine artery ligation [(5)]. Physical occlusion of the uterine blood supply by mechanical tourniquet is one of the most effective interventions to reduce blood loss during transabdominal myomectomy [(6)]. Utero-tonics: such as oxytocin and misoprostol [(7)].

Pharmacologic manipulation of the coagulation cascade: with antifibrinolytic agents such as tranexamic acid and gelatin-thrombin hemostatic sealant [(8)].

Aim of the Work

The aim of this study was to compare between the effect of pericervical uterine artery tourniquet (non-medical) and periperative rectal misoprostol (medical) regarding their efficacy to decrease blood loss during trans- abdominal myomectomy.

PATIENTS AND METHODS

This double blind, Prospective randomized controlled interventional clinical trial was carried out in gynecology department, zagazig university hospital during period from (March 2017 –March 2019).

Study population comprised seventy two women (36 in each group) Calculation of the sample size was done according to data that was obtained from a previous related study [(9)].The total sample of 72 subjects was calculated using open EPI info 6 at power 80% and C.I 95%, These women (20-40) years old, with a total number of ≤ 5 symptomatic uterine leiomyomas, presented with either: abnormal uterine bleeding, pressure symptoms (dysuria, dyspareunia, dyschazia and/or backache), pain (dysmenorrhea and /or dull aching lower abdominal pain) and progressive abdominal enlargement. All leiomyomas were classified as (type (2),(3), (4), (5) or type(6)) according to FIGO classification measuring (>4cm and <10 cm).

Written informed consent was obtained from all participants After detailed explanation of procedure, and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The study was done accordance to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Our exclusion criteria were patients with positive pregnancy test, patient who received pre-operative hormonal therapy such as a GnRH analogue, patient known to be allergic to misoprostol (prostaglandin preparations), patient diagnosed as having cervical, supracervical, broad ligamentray leiomyomas and leiomyomas classified type (0),(1) or (7) according to FIGO classification, patient presented by or with suspected malignant gynecological disease and presence of any associated pelvic pathology other than uterine leiomyomas.

Computer list was used to randomization of participants into group (A) and group (B).

Study design:

Women in the group A (36 participants) underwent Pericervical uterine artery tourniquet:

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); an incision about 1 cm was made in this clear space bilaterally, then A Foley's catheter was applied as tourniquet (or a latex-free tourniquet in a latex-allergic patient) through the

incisions and finally The ends of the tourniquet were protruded anteriorly and pulled tightly and secured the ends with a clamp.

While, women in the group B (36 participants) were received rectal 400 microgram of misoprostol (prostaglandin E2 analogue), 2 tablets of Misotac® (by SIGMA pharmaceutical industries, Alexandria, Egypt) transrectal using a lubricant, 1 hour before the surgery [10].

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.

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.

Difference in weight of towels (in grams) (A) (Weight of soaked towels – weight of dry towels).

Difference between clean empty and full suction bottle containers (in grams) (B).

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

Primary and secondary outcomes were assessed including:

Primary outcome:

Estimate 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 [11].

Secondary outcome:

- Intra-operative or post- operative complications :

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 myoma.

Hematoma formation.

Postoperative fever; temperature >38°C within 24 hours after surgery.

- 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).

Statistical analysis

Investigative report form was used to register all demographic and clinical data, and these data was analyzed by IBM computer using Statistical program for social science version 12. (Level of significance): significant when ($p<0.05$), highly significant when ($P<0.001$).

RESULTS

Our study showed that 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). Our results revealed that there was no statistically significant difference between both groups regarding the main presenting symptoms (table 2). Moreover, our study revealed no statistically significant difference between both groups regarding change in pre-operative HB and HCT level and post-operative HB and HCT (table 3, 5). Comparison between the studied groups regarding the operative data revealed there was no statistically significant difference between both groups regarding estimated intraoperative blood loss, there was no statistically significant difference between both groups regarding the

need for blood transfusion. Moreover, there was no statistically significant difference between both groups regarding operative time. Yet, regarding the myoma site, there was significant difference between the both groups (table 4). Comparison between the studied groups regarding the postoperative data revealed there was statistically significant difference between both groups regarding postoperative complications (postoperative blood transfusion and fever). In the current study, there was no statistically significant difference between both groups regarding hospital stay and drain collection (table 5).

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%)		

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				
Type (3),(4),(5) FIGO staging	16 (44.4%)	12 (33.3%)	10.286 ‡	0.016 (S)
Type (6) FIGO staging	8 (22.2%)	0 (0%)		
type (2) FIGO staging	0 (0%)	12 (33.3%)		
Mixed	12(33.3%)	12 (33.3%)		
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%)		

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 complications	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%)		

Post-operative data	Misoprostol	Uterine tourniquet	Test	P-value (Sig.)
Count	36	36		
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)	115 (100 – 200.5)	-0.737 •	1.743 (NS)

DISCUSSION

The aim of the present study was to compare between the effect of Pericervical uterine artery tourniquet (surgical techniques) and preoperative rectal misoprostol (medical techniques) regarding their efficacy to reduce blood loss during transabdominal myomectomy.

In the current study, the mean age of study population was (32.1± 6.1) years, with rang (27-36). There was no statistically significant difference between the two groups regarding the patients, age.

In the current study (58) patients didn't 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 between the two groups regarding the patient's use of hormonal contraception (COC).

In the present study, 18 patients were nulligravida (NG) (25 %), 18 patients conceived once before (25%) and 36 patients (50%) conceived more than once. 32 patients (44.4%) didn't aborted before, 34 patients (47.3%) aborted once before and 6 patients (8.3%) had more than one abortion. There was no statistically significant difference between both groups regarding the patient's parity and previous abortion.

In the current study, 34 patients had interstitial uterine fibroid (38.9%), 8 patients had subserous uterine fibroid (11.1%) and 12 patients had submucus fibroid (16.7%) and 24 patients had mixed uterinefibroids (33.3%). There was statistically significant difference between both groups regarding myoma site. Although, the difference in myoma site in both groups has no significant affection on blood loss intra operative.

The present study agrees with the results were reported in a study by **Wallach and Vlahos.** [12] Who found that most of the fibroids were intramural (85.4%), followed by subserous (53.4%), and submucous(32%).

In the present study, the most common presenting symptom was heavy menstrual bleeding in 58 patients (80.6%), abdominal pain in 44 patients (61.1%), pressure symptoms in 14 patients (19.4%), and primary or secondary infertility in 26 patients (36.1%). There was no statistically significant difference between both groups regarding the main presenting symptom.

In a study by **Ragab et al.**[3] the most common complaint of the women with uterine leiomyoma was heavy and prolonged bleedings which matches the results of the present study. Besides, diagnosed women indicated more often to have unpredictable and irregular bleedings, also described as frequent periods that appear more often than just every 24 days or bleedings between periods.

The outcomes of the present study was to compare the intraoperative blood loss in two groups , the need for intraoperative blood transfusion, the need for conversion to hysterectomy, operative time (in minutes), intraoperative and postoperative complications, difference between pre and post-operative hemoglobin and hematocrit levels and duration of hospital stay(in days).

In the present study, the difference in the intraoperative blood loss between pericervical mechanical uterine artery tourniquet group and perioperative rectal misoprostol group was 24.5 ml with more blood loss in misoprostol group, yet there was no statistically significant difference between both groups regarding estimated intraoperative blood loss (469.4±104.5, vs. 493±125.2ml respectively) (P= 0.502).

In study of **Alptekin & Efe.**[13] which had Comparison between tourniquet to no-tourniquet use and recorded significant reduction in blood loss in the tourniquet group. The estimated blood loss from the tourniquet group in the study of **Ikechebelu et al.** [14] was (515.7 ± 292.81ml) and this was higher than in the current study.

The results of the present study differ from studies by **Fletcher et al.**[15] and **Helal et al.,**[4] in which the use of mechanical tourniquet produced higher blood loss when compared to other hemostatic techniques as (vasopressin or preliminary uterine artery ligation.

Another study by **EL Sharkawy et al.,**[16] in which (104) women with symptomatic uterine leiomyomas who wished to retain their uteri and needing surgical intervention, (52) patients randomly allocated to receive combined 400 µg rectal misoprostol plus perivascular vasopressin and (52) patients allocated to undergo pericervical tourniquet . Tourniquet group had significant increasing in amount of blood loss comparing with rectal misoprostol plus perivascular vasopressin group (375.7± 292.3 ml) vs. (254.1 ± 185.4ml) subsequently (P= 0.03) and this disagrees with the current study.

In a study by **Christos et al.,**[17] (284 patients) undergoing abdominal myomectomy, where 142 patients received 400 microgram misoprostol vaginally and the other 142 patients received a placebo tablet vaginally. The mean intraoperative blood loss in misoprostol group was (347.5 ml), while in placebo group was (539.3 ml).

Another study by **Kalogiannidis et al.,**[18] in which 67 women undergoing 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). 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.

In the present study, 40 patients required blood transfusion (55.6%); the rate of intra-operative blood transfusion was higher among participants who had pre-operative rectal misoprostol (61.1%) 22 patients, compared to those who had pericervical mechanical tourniquet (50%) 18 patients.

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

While there was no blood transfusion in other study of **(Ragab et al.,**[3] and **Niroomand et al.,**[19]

In the present study there was no statistically significant difference between both groups regarding change in pre-operative and post-operative haemoglobin and haematocrit levels.

In the present study, the mean operative time in the mechanical pericervical tourniquet group was (96.9 min) and in the misoprostol group was (98.1min).So, there was no statistically significant difference between both groups regarding operative time.

In a study of **Christos et al.,** [17] there was no statistically significant difference regarding operative time between the use of vaginal misoprostol and vaginal placebo tablet.

In the present study, the mean postoperative hospital stay in the study population was (3.5± 1.1) days and the mean of post-operative amount of fluid within the drain was (162.6 ± 76.0) ml and there was no statistically significant difference between both groups regarding postoperative hospital stay and drain.

In a study of **Abdel-Hafeez et al.,**[5] 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). This results agree with the present study.

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

The current study disagrees with the results of **Abdel-Hafeez et al.,**[5] in which there was no significant difference between misoprostol group and placebo group as regards postoperative febrile morbidity and other side effects of misoprostol (e.g. diarrhea, nausea and vomiting) this is may be due to the use of regular paracetamol IV in the first 24 h post operatively.

In the current study, no patient had postoperative wound infection, no patients had urinary bladder injury, no patients had broad ligament hematoma, no patients needed conversion to hysterectomy.

CONCLUSION

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

However, a single pre-operative dose of 400 micrograms of rectal misoprostol is as effective as pericervical tourniquet in reducing blood loss in transabdominal myomectomy.

Therefore the choice between of pericervical tourniquet and pre-operative rectal misoprostol is left to the surgeon's surgical preference and capabilities.

Strength and Limitations

The strength of the current study is that it compared pericervical mechanical tourniquet with pre-operative rectal misoprostol (which is uncommon in the literature), the randomized design and objective measurement of the blood loss.

The present study had some limitations

Firstly, only one route (rectal route) of misoprostol was evaluated.

Secondly, the operative time was prolonged falsely in some patients because of measuring from the start of skin incision till skin closure which was not the actual operative time, as in some patients with adhesions need more time in entering the abdomen therefore; operative time should have been measured after entering the peritoneal cavity till closure of the peritoneal cavity.

Thirdly, the range of variation in leiomyoma number , size and site should have been narrowed as it markedly affected the results of operative time and blood loss.

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