Transvaginal Bilateral Uterine Artery Occlusion for Treatment of Symptomatic Uterine Myomas: An Effective Modality in Low Resource Settings

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Abstract: *Objective:* To study the effectiveness and safety of bilateral uterine artery occlusion through the vaginal approach as an alternative treatment modality for symptomatic uterine myomas.

Methods: Sixty-nine premenopausal women with symptomatic uterine leiomyomata were studied. None of them desired further pregnancy underwent bilateral vaginal uterine arteries occlusion. The primary outcome measures were patient satisfaction as regards menstrual blood loss compared with pre treatment loss and operative duration. Secondary outcome measures included postoperative pain, complications, secondary interventions, and failures.

Results: Sixty-three women were completed follow up till 24 months after the procedure. The primary outcomes were encouraging as regards patient satisfaction for post treatment blood loss (90.7 %) and mean operative duration (35 ±9.5 minutes). After 6 months of follow-up, 6 patients resumed heavy periods and interventions needs secondary.

Conclusion: Trans-vaginal occlusion of uterine arteries improved clinical symptoms in the majority of patients.

Keywords: Uterine myoma, Uterine artery occlusion, Vaginal approach.

INTRODUCTION

Uterine leiomyomata are among the most frequent entities encountered in the practice of gynecology. Uterine fibroids occur in 20% to 40% of reproductive age women and are the most common solid pelvic tumors in women [1, 2]. Even though most fibroids are benign and asymptomatic, some patients may complain of abnormal uterine bleeding, pelvic pressure, infertility, and recurrent pregnancy loss. These symptoms may have a negative effect on a patient's physical, emotional, and social well-being [3].

Fibroids are the main indication for 40% to 50% of hysterectomies [4, 5]. Adverse events associated with hysterectomy include significant blood loss, venous thromboembolism, infection, injury to bladder, bowel, or major blood vessels, and death [6].

Over the last few decades, trends in gynaecology have been towards conservative or minimally invasive therapies for common conditions, including exploring alternatives to hysterectomy or myomectomy for symptomatic-fibroids through a critical evaluation of three treatment options: global endometrial ablation, uterine fibroid devascularisation, and magnetic resonance-guided focused ultrasound [7].

Magnetic resonance-guided focused ultrasound (MRgFUS) is a totally non-invasive surgical approach for the treatment of symptomatic uterine

Fibroids It utilizes precisely focused ultrasound waves to generate and maintain temperatures in excess of 56°C within the target tissue, resulting in protein denaturation, cell death and coagulative necrosis [3]. Although clinical studies demonstrate that MRgFUS is a safe, effective treatment for symptomatic uterine fibroids, can be performed as an outpatient procedure; requires no general anesthesia [8], and is cost effective [9]. However not all patients are candidates for the procedure [10] and not free from complications-not [11].

Selective uterine artery occlusion is a global treatment alternative to hysterectomy for women with symptomatic uterine fibroids, in whom other medical and surgical treatments are contra-indicated, refused, or ineffective [12]. Fibroids have been treated effectively by laparoscopic occlusion at the origin of the uterine arteries using vascular clips [13] or bipolar electrocoagulation [14]

Since the uterine arteries are located less than 2 cm away from the vaginal lateral fornices, transvaginal uterine occlusion by surgery or colour Doppler-directed

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ultrasonic probe appears feasible [15,16]. Transvaginal occlusion of the uterine arteries is performed by placing specially designed clamps in the vaginal fornices and, guided by Doppler ultrasound auditory signals, positioning it to occlude the uterine arteries. The clamps are left in place for 6 hours and then removed. Results are preliminary, but this technique may develop into an alternative, noninvasive method for decreasing myoma size [15, 16].

So, our study aims to evaluate the effectiveness and feasibility of surgical transvaginal bilateral uterine arteries ligation in management of symptomatic uterine myomas as an effective alternative in low resourse settings.

MATERIALS AND METHODS

The study was carried out at the Department of Gynecology, Mansoura University, Egypt. Sixty nine (69) premenopausal women referred with abnormal uterine bleeding between March 2009 and March 2011 were included in this trial. Inclusion criteria included women with uterine fibroids causing abnormal uterine bleeding with desire not to have a hysterectomy. Exclusion criteria included pregnancy,a history of deep vein thrombosis, hematocrit < 25%, one or more lower uterine segment fibroids, a history of gynaecologic malignancy or atypical endometrial hyperplasia, active pelvic inflammatory disease or infection, acute or chronic systemic infection,GnRH agonist use in the preceding six months, current use of an anticoagulant, bleeding disorder, severe hematologic or neurologic disease, prior endometrial ablation, prior Uterine Artery Embolization (UAE) or prior Uterine Artery Ligation (UAL), only women with fibroids located above the uterine arteries and not distorting the cervix were included in the study. Suspicion of malignancy (by endometrial sampling and cervical cytology) , submucous leiomyomata with an intracavitary extension of more than 50% (more suitable for hysteroscopic resection) were rulled out. All eligible patients attended a consultation by a gynaecologist, which included a gynaecological examination, ultrasonography, routine endometrial samplig; cervical cytology and office hysteroscopy in suspected uterine cavity lesion(s). Patients were informed about the possible risks and benefits of the treatment and a written consent was obtained from each patient. The study was approved by the local research ethics committee. The procedure was carried out in the operating theatre with the patient placed in lithotomy position under regional or general anaesthia. Vaginal wall retractors were placed allowing visualization of the vaginal fornices and the cervix which was exposed and grasped with a tenaculum. Gentle traction on the cervix was done then the vesico-cervical space was opened and the urinary bladder mobilised up. Then the right lateral vaginal fornix was opened. 1- 1.5 cm incision was done in the medial lower border of the right Mackenrodts ligament and the right uterine artery was identified and skeletonised from the ureter and then a double ligature by aneurysm needle were passed to ligate the uterine artery using poly galactine number 1 vicryl sutures [ETHICON® ltd uk]. Then the procedure was carried on the left side with the same manner on the right one. The Ruta Menorrhagia Severity Scale [17] that allows the patient to assess her own menstrual experience from the preceding three months was used. Low scores indicate a higher quality of life [17]. The participants were encouraged to use the same type of sanitary pads during the study period. The study participants were surveyed in relation to their present leiomyoma-related symptoms before treatment and after 1, 3, 6, 12 and 24 months, respectively. Clinical failure was defined as persisting symptoms requiring secondary treatment or no improvement at the 6-month follow-up. Postoperative pain and nausea during the hospital stay were recorded on post operative charts. The resident doctors were asked to fill in the level of pain and nausea patients experienced every 4 hours during the first 24 hours in the hospital and every 6 hours during the next 24 hours or until the patient left the hospital. The analgesic regimen consisted of nonsteroidal anti-inflammatory drugs and paracetamol-codeine combination in fixed doses. Adverse events were also recorded for each patient during the hospital stay and during outpatient visits after 1, 3, 6, 12 and 24 months. All subsequent surgical and medical interventions, as well as readmission to the hospital or prolonged hospitalization were recorded as adverse events. Clinical failure was defined as persistent symptoms requiring secondary treatment or no improvement at the 6-month follow-up. Doppler study of uterine arteries was done 48 hours after the procedure for all participants. Statistical analysis was performed with SPSS 16.0 (Chicago, IL), and the data are presented as mean values for normal distributed data and as median values for skewed data. A significance level of 0.05 was used for all tests. Power of the study and sample size was acheived using PASS 2008 (Power analysis and sample size, NCSS, Kaysville, UT, USA). So, a sample size of 69 patients, giving a power of 93 % (18, 19).

RESULTS

This study includes sixty nine patients all underwent bilateral vaginal occlusion of main uterine arteries and they were followed up for 3, 6; 12 and 24 months for the improvement of the symptoms. Only sixty- three patients completed the 24 months follow up. Demographic criteria of the studied group listed in Table **1** showing that the mean age of the studied group was 49 years ± 4.5 SD , the mean parity was 4 ± 2.2 SD, BMI was 24 ± 3.15 SD, myoma numbers were 4 ± 2.9 SD; myoma(s) volume 122 ±72.3 SD ml and uterine volume 233 ± 98.4 SD ml. Table **2** reporting the post operative complications and needs of post operative analgesia. Only three cases (3/69) 4% had bladder injury and corrected immediatly intra operative and nine patients (9/69) 13.1% needs non steroidal anti inflamatory Drugs (NSAID) + morphine. Blood loss and operative duration were listed in Table **3** showing that mean operative time was 35 ± 9.5 minutes and only three patients (3/69) 4% needed blood transfusion. Clinical outcomes after follow up for 3, 6, 12 and 24 months were studied in Table **4** showing greet improvement of the symptoms with 90.7 % reduction in bleeding, 81 % improvement in pelvic pressure, 83 % improvement in dysmenorrhea; 88 % relief of all symptoms and 90 % over all satisfaction after 24 months follow up. Clinical failure occur in six cases after six months follow up needing hysterectomy.

Table 1: Demographic Characteristics of the Study Group

Mean ± SD	Total Number (69)	Characteristics
49 ± 4.5	11 (15.9%) 37 (53.6 %) 21 (30.5 %)	Age 35 years 35-45 years 45 years
4 ± 2.2	9 (13.1 % 43 (62.3 %) 17 (24.6 %)	Parity 0–2 2-5 5
24 ± 3.15	38 (55 %) 21 (30.5 %) 10 (14.5 %)	BMI 19–24 25-29 29
	4± 2.9	Number of myomas
	122 ±72.3	Size of myoma(s) / ml
	233 ± 98.4	Volume of the uterus /ml

Table 2: Postoperative Complications and Analgesia Administration in the Study Group

Total Number (69 = 100 %)	Operative Complications and Postoperative Analgesia Given
66 (95.6 %) 3 (4.4 %) 0 (0.0 %)	Complications:- No Complication Bladder injury Ureteric injury
23 (33.3%) 37 (53.6%) 9 (13.1%)	Post operative analgesia Placebo NSAID NSAID + morphine

Table 3: Average Duration of Operation and Blood Loss in the Study Group

Outcomes	Total
Operative Duration / Minutes	**35 ± 9.5 Minutes**
Blood loss Mild (150 ml) Moderate (150- 300 ml) Severe (300 ml) Needs of blood transfusion	 63 (91.3%) 4 (5.8 %) 2 (2.9 %) 3 (4.3 %)

DISCUSSION

Although with the advent of the science and technologies which approved by Food and Drug Association in the field of minimally invasive surgery and its effectiveness like myolysis, UAE, UAL, Uterine Artery Coagulation (UAC); MRgFUS and transvaginal incisionless doppler guided temporary uterine artery occlusion in management of symptomatic fibroids [8,13-16, 20]. These are not suitable for low resource settings. So, we did our study and compared our results with other studies as regards improvement of myoma related symptoms and patient satisfaction as a primary goal. In our study there was improvement in all myoma related symptoms and patient satisfaction at the six- month follow up there is improvement in bleedig by 84%, pelvic pressure by 57%, pelvic pain by 59%; relief in all symptoms by 64% and over all satisfaction 74% and these agree with Lee et al and Vilos et al [13, 21] and higher than that of Yen et al [22], and this may be explained by smaller sample size in his study. While at one year follow up our results comparable with Spies et al [23] and Prone et al [24]. At two years follow up, there was improvement in bleedig by 90.7%, pelvic pressure by 81%, pelvic pain by 83%; relief in all symptoms by 88% and over all satisfaction 90% and these comparable with Holub et al [25]. As regards the operative duration time can not be compared with other new technologies used in management of symptomatic myomas like MRgFUS, UAC, UAL, UAE; myolysis or even temporary uterine arteries occlusion which may take from minimally six to nine hours [21]. Our study concluded that three cases

Table 4: Clinical Outcome after Treatment with Follow up for Two Years

24 months number (63)	12 months number (63)	6 months number (69)	3 months number (69)	Symptoms Improvements
90.7%	89.7%	84%	77%	Bleeding reduction
83%	69%	59%	50%	Dysmenorrhea
81%	77%	57%	49%	Reduction of pelvic pressure
88%	81%	64%	59%	Relief of all symptoms
90%	88%	74%	67%	Satisfaction
-	-	6	-	Clinical failure

only had intra operative bladder injury, nine cases received NSAID + morphia as post operative analgesics and three cases had severe blood loss entailing blood transfusion.

CONCLUSION

Trans vaginal bilateral uterine arteries occlusion is safe, feasible; simple and an effective alternative management of symptomatic uterine myomas in low resourse settings leading to improvement in clinical symptoms in the majority of patients**.**

There is no conflict of interest in this study

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