



A Case-Based Study on the Effectiveness of Embospheres as Embolizing Agent in the Treatment of Symptomatic Uterine Fibroids

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Abstract: **Introduction:** Embolization of the uterine arteries (UAE) has been approved as a minimally invasive technique for the treatment of uterine fibroid and maintaining fertility; different agents are used in this technique; embospheres have nowadays become widely used in many centers. Aim: assess the effectiveness and safety of Embospheres as Embolizing agents in treating symptomatic uterine fibroids among Iraqi patients. **Methods:** This was a mixed retrospective-prospective study conducted at Ibn Sina Hospital; the study included 17 patients who were managed and followed up during the period 2018 - 2020 included 17 Iraqi women with symptomatic uterine fibroids and were managed with embolization of uterine arteries using Embosphere as an embolization agent followed for six months by MRI to monitor changes in size & IV contrast enhancement. Results: The mean age of the patients was 39.5 (range: 266-49) years. Single fibroids were reported in 70.6% of the cases and multiple fibroids in 29.4%, the median number of fibroids was significantly reduced after UAE, ($P < 0.05$) and the median size reduced by more than 50%, from 11 cm to 5 cm after UAE, ($P < 0.05$). More than 70% of fibroids decreased in size, and 17.6% disappeared. After UAE, during the follow-up period, 17.6% of women got pregnant safely. Unfortunately, two patients did not get the benefit. **Conclusions:** Embospheres were safe and effective as an Embolizing agent in treating symptomatic uterine fibroids with good outcomes and no serious adverse effects or complications.

Key Words: uterine fibroid; embolization; embolization agents; embosphere

I. INTRODUCTION

Uterine Fibroid, also known as uterine myoma, is a benign smooth muscle tumor of the uterus; it is a fairly common disease; many women have no symptoms, but others may have painful and heavy periods in addition to other symptoms. The disease is diagnosed in 20% of thirty-year-old women [1]. For a long time, it can be transformed to malignant under certain conditions [2]. Until recently, there is no single approach for the treatment of fibroids, and many options are implemented [3], including medications, non-invasive techniques, minimally invasive procedures such as uterine artery embolization, and surgical procedures such as abdominal myomectomy and hysterectomy. Outcomes of treatment options varied widely; gynecologists mainly aimed to preserve the uterus and reproductive quality among affected women; therefore, choosing the treatment option represents a challenge in the daily practice of gynecologists to make such decisions and discuss the treatment options with their patients [4], [5]. A uterine fibroid is a monoclonal tumor arising from the myometrial smooth muscle cells and fibroblast during the

reproductive age of women [6]. The tumor includes a significant amount of the extracellular matrix, which has a rather complex structure, and the interstitial component of uterine fibroid includes collagen, fibronectin, and proteoglycans, according to the International Federation of Gynecology and Obstetrics (FIGO). Fibroids are classified as intramural, sub serosal, or submucosal. Other classification according to a number of fibroids [6], [7]. Uterine fibroid is not uncommon, where out of 100 women who underwent hysterectomy, 77% of cases, uterine fibroid is found, including tumors less than 1 cm in diameter [8]. Today, uterine fibroid is viewed not only as a medical problem with all the difficulties of diagnosis and treatment but also as a financial problem that is a serious burden on the family. Moreover, patients with uterine fibroids also have a social problem since reproductive disorders associated with uterine fibroids significantly reduce the quality of life [9]–[11].

Indications for surgical treatment of fibroids are rapid fibroid growth into the uterine cavity according to the data of the last 2-3 examinations; size of fibroid more than 14

cm; severe uterine bleeding and anemia, signs of pressure on other organs (dysfunction of the intestines, kidneys, bladder); and planning for pregnancy [3], [4], [12]. The choice of the volume, access options, and the timing of surgical treatment depends on many factors (the patient's desire to preserve reproductive and menstrual function, the size of the uterus, the number of nodes, the presence of an adhesive process in the abdominal cavity, concomitant somatic pathology, etc.) [3], [4], [12]–[14].

Uterine artery embolization (UAE) is a minimally invasive intervention based on working with the vessels supplying the myomatous nodes. The surgeon makes one puncture in the groin area. Under local anesthesia, a polymer substance is injected into the arteries to block the blood flow. The operation takes about 30 minutes. Myoma shrinks within 3–9 months [13], [15]–[19]. Indications for embolization of the uterine arteries are fibroid more than 2 cm, ineffective conservative treatment, profuse menstruation, and contraindications to general anesthesia [19], [20]. Contraindications for UAE are subserous and submucous uterine myoma on a thin base, large nodes; inflammatory diseases of the pelvic organs, allergy to contrast, borderline or malignant diseases of the pelvic organs; disorders of the coagulation system, impaired renal function, heart failure [20], [21].

II. BENEFIT OF UAE

Healthy uterine tissue is unaffected; a healthy uterus restores blood circulation after 6–8 hours. Short-term hospital stays of almost 18 hours, Low risk of relapses and complications, and preservation of reproductive function [21]. The UAE had only a few limitations regarding relatively expensive consumables, and a highly qualified doctor is required with special imaging equipment [22].

Embolization of the uterine arteries (UAE) is carried out under X-ray control. It is performed under local anesthesia and is considered as much less invasive than open or laparoscopic surgery to remove uterine fibroids (myomectomy) or the entire uterus (hysterectomy). General anesthesia is not required during the operation; embolization takes place with almost no blood loss. Patients can return to normal life much earlier than with traditional surgery [16]. In UAE, the embolizers go directly to the uterine myoma itself. The particles block the arteries that supply blood to the fibroid and cause it to degrade [23].

Through the catheter, embospheres are delivered to the tumor - microparticles that swell in the arteries and stop the access of blood, enriched with oxygen and nutrients, to the tissue of the myomatous node. Myoma is deprived of nutrition. As a result of this effect, death (ischemia) of all myomatous nodes occurs. Their growth stops, and regression starts, that is, a decrease in the size of the nodes and their transformation into connective tissue until they disappear completely [24]. Almost 90% of women with fibroids experience symptom relief after embolization [23].

III. EMBOLIZATION DRUGS (EMBOLIC AGENTS)

Are small particles injected through a small catheter into the uterine arteries which then flow and reach the uterine fibroids and lodge in the feeding arteries of these fibroids the procedure performed with a fluoroscope by expert professional radiologist. There are different types of embolic agents available to use and are FDA approved [18], [23], [24], among these agents:

BEAD BLOCK

Which is biocompatible poly vinyl alcohol (PVA), composed of spherical particles of different size ranged from 100–1200 μm [25].

CONTOUR EMBOLIZATION PARTICLE

PVA irregular shaped flakes, size ranged 45 to 1180 μm [26].

BEARING NSPVA EMBOLIZATION PARTICLE

PVA irregular shaped particles, 45 - 1180 μm in size.

HYDROPEARL MICROSPHERE

Polyethylene glycol, spherical 75 - 1100 μm particles [27].

EMBOZONE MICROSPHERE

Hydrogel microsphere with Polyene-F coating, spherical precisely calibrated of 40 - 1300 nm [28].

EMBOSPHERE

Trisacryl with gelatin spherical with size from 40–1200 nm. Since the main goal of the intervention is the embolization of the arteries of the myomatous node and the periphyroid plexus, the vessels of which have an average diameter of not more than 500 nm, synthetic hydrogels of the appropriate size are used for UAE. For their manufacture, dry particles of polyvinyl alcohol (PVA) with a diameter of 500–710 nm are most often used, in rare cases - 355–500 nm or 150–355 nm, which are proportionally diluted in a mixture of contrast agent and isotonic solution until a uniform suspension of the drug is achieved immediately before intervention [18], [23], [24], [29], [30].

IV. PATIENTS AND METHODS

STUDY DESIGN AND SETTING

Upon presentation, all patients exhibited symptoms related to their condition. The study period saw the admission of patients with varying numbers and sizes of uterine fibroids, all of whom were considered candidates for uterine artery embolization using Biosphere as the embolic agent. However, certain conditions necessitated exclusion from the study. These included pregnancy, an existing pelvic or gynecological infection, postmenopausal status, a known adverse reaction to contrast media, any form of coagulopathy, renal insufficiency, and a history of previous pelvic radiation. These criteria were established to ensure the safety and appropriateness of the treatment for each patient.

PROCEDURE

All patients were prepared well before the procedure by thorough clinical examination and entire history taking. Routine investigations were performed, and antiemetics, antibiotics, IV fluid, and analgesics were used accordingly.

Uterine artery embolization was performed by a professional expert interventional radiologist in a fully equipped angiographic unit. A standard technique and protocol were applied and followed. The right common femoral artery was used to access the uterine artery, and a 2.7 co-axial catheter embolization was performed on each side to complete stasis. After 60 60-second periods of no flow observed, it means complete stasis.

STATISTICAL ANALYSIS

Data were managed, analyzed, and processed using the Statistical Package for Social Sciences (SPSS) version 26. Variables are presented as mean, median, standard deviation, range, frequencies, and percentage. Data was compared before and after UAE using non-parametric statistical paired tests. At a level of significance of ≤ 0.05 , the difference or change is considered significant.

V. RESULTS

On examination and investigation, one patient had small atrophied ovaries, and another patient had a right ovarian cyst. Regarding the number of fibroids, single fibroids were the most frequent, contributing 12 (70.6%) and only five women (29.4%) with multiple fibroids Figure 1. Regarding the enhancement, as shown in Table 1, eight fibroids had mild enhancement before UAE and reduced to 6 after UAE. However, the change was not significant (P value > 0.05). The median number of fibroids before UAE was 5; after UAE, it was 2, with a statistically significant reduction in fibroids (P value = 0.022). The median size of fibroids reduced from 11 cm before to 5 cm after UAE with significant change (P value = 0.001).

On the other hand, the median size of the largest fibroid also decreased significantly after UAE from 22 to 17 cm. So, as for the median size of the smallest fibroid, which reduced from 2.4 to 1.5, however, the difference was statistically not significant (P value > 0.05), Table 1. Furthermore, a significant change was reported in the mean size of fibroids from 10.26 cm before UAE to 5.71 cm after UAE (P value = 0.006). From another point of view, after UAE, 12 (70.6%) of fibroids have been decreased in size, and 3 (17.6%) disappeared, while in two patients, no benefit reported, Table 1. The overall outcome after UAE among the studied group revealed that 12 patients (70.6%) were better and satisfied, three women (17.6%) got pregnant, and two patients (11.8%) have no change, (Table 1 and Figure 2).

VI. DISCUSSION

Uterine fibroids are among the most frequent tumors in a woman's reproductive system, affecting their health, quality of life quality, and fertility [30], [31].

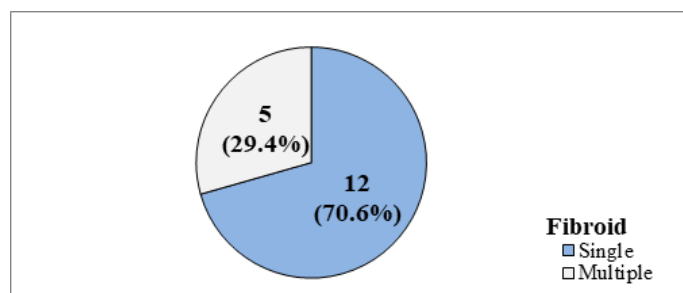


FIGURE 1: Distribution of the Studied Group According to the Number of Fibroids

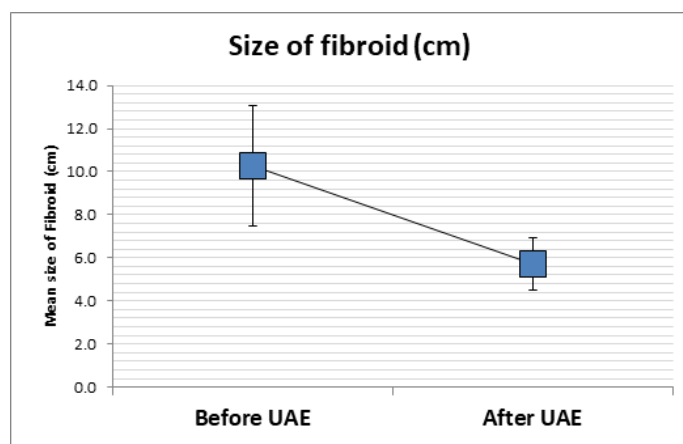


FIGURE 2: Graphical Presentation of the Change in Mean Size of Fibroid after UAE

In recent years, a relatively new method of treating uterine fibroids - endovascular embolization of the uterine arteries (UAE) - has entered clinical practice as a minimally invasive technique for treating uterine fibroids and maintaining fertility. Many institutions approve of this procedure. Technical mistakes are rare, and the process is rarely repeated [32], [33]. Given the different outcomes in the UAE, there is no risk of long-term consequences [34]. There are different agents and methods available for embolization, but the effectiveness of embolization is still under debate [24], [33], [35]; therefore, in this work, we aimed to assess the effectiveness of atmospheres as an embolizing agent in the treatment of symptomatic uterine fibroids, a total of 17 Iraqi women were eligible for UAE and enrolled in this study, majority of the patients were older than 30 years with a median age of 40, this is expected as the majority of uterine fibroid patients diagnosed after the age of 30s [12], [36].

Among the studied group, more than two-thirds had a single fibroid. However, the median number of fibroids before UAE was five and reduced to only 2 after UAE; these findings agreed with that reported by Keung *et al.* [37], who found a significant reduction in several fibroids of 6 before UAE.

In the current study, the size of fibroids decreased significantly after UAE compared to its baseline (before UAE) values; this indicated the effective UAE procedure in general

Enhancement	Before UAE		After UAE		P. value
	No.	%	No.	%	
No enhancement	9	52.9	11	64.7	#
Mild enhancement	8	47.1	6	35.3	#
Total	17	100.0	17	100.0	
Median number of fibroids	5.0		2.0		*
Median size (cm)	11.0		5.0		*
Median size of largest fibroid (cm)	22.0		17.0		*
Median size of smallest fibroid (cm)	2.4		1.5		#
Change in size					
Mean (cm)	10.26		5.71		
Status of fibroid			No. of patients	%	
Decrease			12	70.6	#
Totally disappeared			3	17.6	
No benefit*			2	11.8	
Total			17	100.0	
Outcome					
Better, patient satisfied			12	70.6	#
Got pregnancy			3	17.6	
No change			2	11.8	
Total			17	100.0	

In these 2 patients, fibroid removed by surgery

TABLE 1: Enhancement, Size, and Characteristics of Fibroids before and after UAE

by reducing the size of the fibroids; furthermore, fibroids totally disappeared in 3 patients (17.6%). Nonetheless, two patients did not get the benefit. On the other hand, the overall outcome after UAE was good enough to be considered, where 12 patients had decreased fibroid size and were better and satisfied with this procedure result; interestingly, three women got pregnant after UAE. Nonetheless, 2 patients had no change. These findings are close to those reported in previous studies that used the biosphere as an embolizing agent; Abramowitz et al. [35] compared the atmosphere to other agents and found that the Embosphere resulted in a significant reduction in uterine volume and size of uterine fibroid.

Another study by Vaidya et al. [24] compared different embolizing agents and found that UAE is a safe technique and atmosphere is an excellent agent with good outcomes. In their retrospective study compared atmosphere with Beadblock in 70 and 55 patients, respectively, their clinical assessment showed improvement in their symptoms in both groups; follow MRI revealed no significant difference between these two agents in reduction of uterine volume or fibroid size, where both agent result in good reduction in volume and size after UAE, however, reduction in residual enhancement occurred in 16% of biosphere group, which close to our findings.

Liaw et al. [38] reported no significant difference between the traditional atmosphere and end EmboGold regarding symptoms and patient satisfaction. Both agents improved the outcome significantly when used in UAE.

Keung et al. [37] included biosphere and three other agents and compared their effectiveness as embolizing agents; Abramowitz et al. [35] documented that bead block and Contour SE were better than atmosphere about the degree of infarction at MRI follow up. Earlier studies have assessed the differences between embolic comparing pre and post-

embolization enhancement. In our study, we did so. However, there was a change in enhancement after embolization, but it did not reach statistical significance, which could be attributed to the small sample size [28].

Fortunately, no serious adverse effects or complications were reported among our patients, and good outcomes were obtained regarding improvement in clinical symptoms, patient satisfaction, and fertility; this reflects the effectiveness and safety of UAE with embosphere in treating Uterine fibroid. However, the only limitation in our study attributed to the lack of a control group using other agents; this was due to performing this study in only one center; however, further studies using multiple centers and a larger sample size could resolve this issue.

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CONFLICT OF INTERESTS

The authors declare no conflicts of interest.

AUTHORS' CONTRIBUTIONS

All authors contributed equally to this paper. They have all read and approved the final version.

CONSENT

Informed consent was obtained from all participates in the study as needed.

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