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CLINICAL INVESTIGATION

Uterine Artery Embolization in 101 Cases of Uterine Fibroids: Do Size, Location, and Number of Fibroids Affect Therapeutic Success and Complications?

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Abstract The purpose of this study was to evaluate whether the size, location, or number of fibroids affects therapeutic efficacy or complications of uterine artery embolization (UAE). Patients with symptomatic uterine fibroids ($n = 101$) were treated by selective bilateral UAE using 500- to 710-μm polyvinyl alcohol (PVA) particles. Baseline measures of clinical symptoms, sonography, and MRI taken before the procedure were compared to those taken 1, 3, 6, and 12 months later. Complications and outcomes were analyzed for associations with fibroid size, location, and number. Reductions in mean fibroid volume were similar in patients with single (66.6 ± 21.5%) and multiple (67.4 ± 25.0%) fibroids (p-value = 0.83). Menstrual improvement occurred in patients with single (93.3%) and multiple (72.2%) fibroids ($p = 0.18$). Changes in submucosal and other fibroids were not significantly different between the two groups (p's > 0.56). Linear regression analysis between primary fibroid volume as independent variable and percentage reduction of fibroid volume after 1 year yielded an R^2 of 0.083 and the model coefficient was not statistically significant ($p = 0.072$). Multivariate regression models revealed no statistically or clinically significant coefficients or odds ratios for three independent variables (primary fibroid size, total number, and fibroid location) and all outcome variables (percent reduction of uterus and fibroid volumes in 1 year, improvement of clinical symptoms [menstrual, bulk related, and urinary] in 1 year, and complications after UAE). In conclusion, neither the success rate nor the probability of complications was affected by the primary fibroid size, location, or total number of fibroids.

Keywords Leiomyoma · Uterine artery embolization

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Introduction

Uterine artery embolization (UAE) is an alternative treatment for symptomatic uterine fibroids. Uterine arteries provide the predominant vascularization for these benign tumors [1]. Ravina et al. reported the first study showing that embolization of these arteries leads to necrosis of fibroids [2]. In many reports, menorrhagia was improved in 85–95% of patients, and bulk symptoms were improved in 70–90% of patients after UAE [3–7]. Spies et al. showed a mean reduction in fibroid volume of 57.8% (95% CI, 52.7–62.8) at 12 months and a mean reduction in uterine volume of 39.4% (95% CI, 34.6–44.2) at 12 months [8].

There are different factors for determining whether UAE is indicated. Katsumori et al. [9]reported that the baseline fibroid diameter is not a risk factor for patients undergoing UAE; however, the importance of the size of a fibroid is still a matter of debate.

The objectives of this study were to evaluate the efficacy and complication rate of UAE in the treatment of symptomatic uterine fibroids in a Middle Eastern population and to determine whether tumor size, location, or total number of fibroids affects therapeutic efficacy and complications.

Materials and Methods

Between September 2001 and April 2006, 114 premenopausal women were referred to our center by a gynecologist for treatment of symptomatic fibroids. Unilateral UAE was carried out in 13 of the 114 patients (11.4%). These failures were due to the following.

1. Missing uterine artery in one side, with no detectable collateral feeders from ovarian arteries ($n = 2$).
2. Unilateral technical failure ($n = 11$). Three of these patients had one highly tortuous uterine artery that could not be embolized. Among the eight remaining cases, five failed in the first 6 months of the study.

All 101 remaining patients (88.6%) underwent bilateral uterine artery catheterization and embolization. Therefore, 101 patients were entered in the study. The baseline demographic data are presented in Table 1. All patients were counseled about the risks and benefits of UAE and other alternative treatments. Informed consent was obtained from each patient before UAE.

Each patient presented with abnormal menstrual bleeding, bulk-related symptoms, or a combination of both. Bulk-related symptoms included pelvic pain, pelvic pressure or heaviness, and urinary symptoms. We assessed menorrhagia with the Ruta Menorrhagia Questionnaire [10]. All patients included in the study were symptomatic, failed medical therapy, and refused hysterectomy when indicated. Exclusion criteria included current pregnancy, endometrial hyperplasia, cervical, uterine, or ovarian carcinoma, pelvic inflammatory disease, endometriosis, adenomyosis, and presence of any contraindications for angiography. Among patients who wanted to preserve their fertility, only those who were candidates for hysterectomy or extensive myomectomy were included.

All patients underwent gynecologic examination, transabdominal ultrasonography (GE 200; GE, USA; Convex probe, 2.5–5 MHz), and magnetic resonance imaging (MRI). MRI included transverse, sagittal, and coronal T2-weighted turbo spin-echo imaging and sagittal T1-weighted two-dimensional fast low-angle shot imaging with fat saturation before and after administration of gadolinium. (1.5 T, Signa; GE).

The dominant fibroid (largest fibroid) and the uterine volumes were calculated using a prolate ellipse formula (length × depth × width × 0.5233).

We scheduled all patients to be followed up at 1, 3, 6, and 12 months after the procedure by questionnaire survey and ultrasonography. All patients had at least one follow-up; 78 patients were followed up at 1 month, 69 at 3 months, 69 at 6 months, and 41 at 12 months. Furthermore, we evaluated patients by MRI with and without gadolinium injection at 6 and 12 months after the UAE.

Table 1 Baseline data ($n = 101$)

Category	Value
Mean age ± SD, yr (range)	36.09 ± 6.6 (20–49)
Marital status, *n*	
Married	49 (48.5%)
Unmarried	52 (51.5%)
Pregnancy history, *n*	
0	61 (60.4%)
≤1	40 (39.6%)
1	10 (9.9%)
2	16 (15.8%)
>2	14 (13.8%)
Symptom history, *n*	
Menorrhagia	79 (78.2%)
No impairment of normal activity	36 (35.6%)
Some impairment of normal activity	43 (42.7%)
Dysmenorrhea	62 (61.4%)
Urinary	40 (39.6%)
Bulk	59 (58.4%)
Previous treatment, *n*	
None	33(32.7%)
Hormonal therapy	55 (53.4%)
Myomectomy	8 (7.9%)
Number of fibroids in a patient	
1	41 (40.5%)
2–5	28 (27.7%)
>5	32(31.6%)
Location of dominant fibroid, *n*	
Intramural	29 (28.7%)
Subserosal	10 (9.9%)
Submucosal	3 (3%)
Pedunculated subserosal	1 (1%)
Intramural and subserosal	30 (29.7%)
Intramural and submucosal	17(16.8%)
Transmural	4 (4%)
Mean uterus volume, cm^3 (range)	600.5 ± 657.7 (84.6–4656.7)
Mean dominant fibroid volume, cm^3 (range)	248.1 ± 365.1 (9.1–2618.2)

Embolization The angiography system was a GE DEX DSA with 1200 MA and 140 KVP. All patients underwent catheterization from a right femoral approach using a 4- or 5-Fr Cobra catheter without microcatheters. Aortography was performed prior to pelvic arteriography with a pigtail catheter; the catheter was placed in the abdominal aorta at the level of the renal arteries. Then selective catheterization of uterine arteries was performed. The tip of a 4- or 5-Fr Cobra catheter was positioned beyond the junction of the

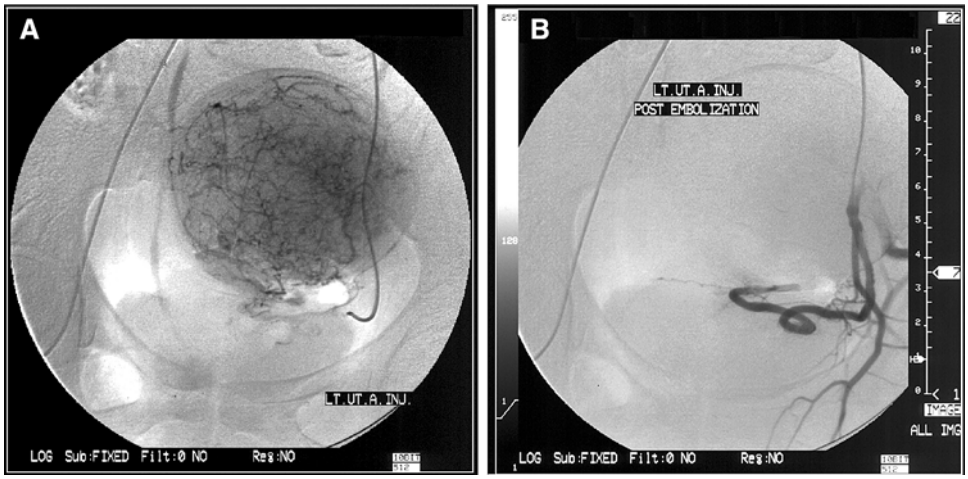

Fig. 1 (**A**) Selective catheterization of left uterine artery shows tumoral blush and hypervascularity of fibroids. (**B**) After embolization the contrast injection demonstrates cessation of flow in the fibroid

descending and horizontal portions of each uterine artery. Embolization was performed using 500–710-μm polyvinyl alcohol (PVA) particles (Contour; Boston Scientific, Boston, MA, USA) injected manually under fluoroscopic control. The PVA particles were slowly injected through the catheter. The injection was stopped upon cessation of arterial flow to avoid retrograde reflux of particles and infiltration to other internal iliac artery side branches (Fig. 1). When an anastomosis was encountered between the uterine and the ovarian arteries, the catheter tip was positioned distal to the anastomosis; in some cases, we used gel foam particles to occlude the anastomosis temporarily and then UAE was performed. We made our gel foam particles from sponge sheets (Gelitaspon; Gelita Medical BV, Amsterdam, Netherlands). We cut the sheet into small fragments with scissors.

Postembolization angiography was performed for the evaluation of redistribution.

Before the UAE procedure, each patient was prophylatically given a single intravenous dose of cefalotin (1 g) and gentamycin (80 mg). Immediately after the procedure, all patients were admitted to an observation unit for at least 4 h. Patients with refractory pain were admitted overnight. Pain was controlled with intramuscular and intravenous pethidine (25–50 mg) or morphine sulfate (10 mg). On discharge, patients were given prescriptions for ibuprofen (400 mg orally four times daily) and diclofenac sodium (50 mg suppository every 6 h, if necessary).

Re-embolizations were required in four cases; two were due to technical failure, in one there were multiple ectopic arterial branches feeding the fibroid, and the other was required for the treatment of massive uterine bleeding after fibroid expulsion (as previously reported [11]).

Statistical analysis SPSS version 11.5 was used for statistical analyses. Statistical analyses were performed with the paired t-test, the Friedman test, Pearson's correlation coefficient test, and linear and logistic regression models. A probability value of <5% ($p < 0.05$) was considered significant.

Results

Procedure Twelve months after the procedure, fibroid volume was reduced by $67.3 \pm 23.0\%$ ($n = 41$; $p < 0.0001$), and uterine volume was also significantly reduced (Table 2). The patients had experienced significant improvements in symptoms, including menorrhagia, urinary symptoms, and bulk related symptoms, at 12-month follow-up (all p's < 0.0001; Table 2). Vomiting was the most common complication after the procedure, occurring in 49 patients (48.5%; Table 2). Only 11% of the patients showed partial fibroid enhancement at the 1-year follow-up MRI.

Fibroid number We assessed whether there were associations between fibroid number and outcome measures including size reduction of fibroid and uterus, patients' symptoms, and postprocedure side effects. For this assessment we categorized the patients into two groups: those with one fibroid ($n = 41$ patients) and those with multiple fibroids ($n = 60$ patients). Treatment efficacy was similar for these groups, as shown in Table 3. The uterine volumes were significantly more reduced in patients with single compared to those with multiple fibroids ($p = 0.017$). However, there were no significant differences between groups in terms of changes in fibroid volumes ($p = 0.83$), improvements in menorrhagia ($p = 0.18$), improvement of other symptoms (all p's > 0.5), or frequency of postprocedure side effects (fever, severe pain, severe vomiting, and fibroid delivery; all p's > 0.2).

Table 2 Uterine artery embolization (UAE) outcomes

		Before UAE (cm^3)	After UAE (cm^3)	Mean percent	*p*-value
Size reduction	Uterus volume ($n = 40$)	612.1 ± 465.3	354.5 ± 312.8	40 ± 29.9	<0.0001
	Fibroid volume ($n = 41$)	274.3 ± 315.6	70.6 ± 74.2	67.3 ± 23.0	<0.0001
Patients' symptom improvement ($n = 101$)	Menorrhagia			81.8	<0.0001
	Urinary symptoms			72.2	<0.0001
	Bulk related symptoms			84.6	<0.0001
Complications after UAE ($n = 101$)	Vomiting			48.5	–
	Fever			29.7	–
	Pain			29.7	–
	Expulsion			16.8	–

Fibroid location We assessed whether there were correlations between the fibroid location and the outcome measures mentioned above. For this assessment we categorized the patients into two different groups: those with submucosal fibroids and those with nonsubmucosal fibroids ($n = 74$). Treatment efficacy was similar for these groups, as shown in Table 3. There were no significant differences between groups in terms of changes in mean fibroid volume ($p = 0.56$), changes in mean uterus volume ($p = 0.51$), improvements in menorrhagia ($p = 0.56$), improvement of other symptoms (all p's > 0.27), or postprocedure side effects (all p's > 0.12).

Primary fibroid size We assessed whether there were any correlations between changes in fibroid volume and primary fibroid size using linear regression. In this regression model the percentage reduction of the fibroid size after 12 months was the dependent variable and the primary fibroid size was the independent variable. The model showed that there was no significant correlation between the two parameters ($R^2 = 0.083$, unstandardized model coefficient $= 2.1 \times 10^{-5}$, $p = 0.072$).

Multivariate regression analyses We assessed whether the fibroid size, location, or number was correlated with the outcome variables using multivariate regression analysis. Each outcome was a dependent variable, and fibroid size, location, and number were the three independent variables. In the case of fibroid and uterus volume reductions, we used multivariate linear regression, and for the other outcomes we used multivariate logistic regression. Only marginally significant correlations were found between fibroid size and improvements in menorrhagia ($p = 0.051$) and urinary symptoms ($p = 0.047$), as shown in Table 4. No correlations were evident between the three independent variables and changes in fibroid volume (all p's > 0.18; $n = 39$). Except for the marginal correlations mentioned above there were no significant odds ratios for the three independent variables and menstrual bleeding after 12 months (all p's > 0.05; $n = 32$), improvement of bulk related symptoms, urinary symptoms after 12 months, or any of the complications after UAE (all p's > 0.07). Considering that the odds ratios were only marginally significant at best, none of the variables were statistically or clinically significant in any of the models.

Table 3 Efficacy and complications of UAE according to the number and location of fibroids

Parameter	Comparisons between different numbers of fibroids		*p*-value	Comparisons between different locations of fibroids		*p*-value
	Single fibroid	Multiple fibroids		Submucosal	Other sites	
Reduction in uterine size, 0–12 mo (mean ± SD)	51.0 ± 26.2	31.0 ± 30.5	**0.017**	44.8 ± 29.6	37.8 ± 30.6	**0.51**
Reduction in fibroid size, 0–12 mo (mean ± SD)	66.6 ± 21.5	67.4 ± 25.0	**0.83**	63.8 ± 26.7	68.3 ± 22.2	**0. 56**
Improvement in menorrhagia, 0–12 mo (%)	93.3	72.2	**0.18**	100	76.9	**0.56**
Improvement in urinary symptoms, 0–12 mo (%)	75	70	**0.95**	100	64.3	**0.27**
Improvement in bulk symptoms, 0–12 mo (%)	91.7	78.6	**0.59**	100	80	**0.54**
Fever after procedure (%)	32.3	42.6	**0.36**	36.8	39.7	**0.82**
Pain after procedure (%)	30.3	42.6	**0.26**	21.1	40.7	**0.12**
Vomiting after procedure (%)	56.3	67.4	**0.31**	68.4	61.4	**0.58**
Delivery (fibroid expulsion) after procedure (%)	22.5	13.8	**0.26**	20	16.2	**0.69**

Table 4 Multivariate regressions for correlations between outcomes and primary fibroid size, location, and number

Outcome variable	Size of primary fibroid	*p*-value	Fibroid location	*p*-value	Fibroid number	*p*-value
	Multivariate linear regression: model coefficient					
Model for volume reduction						
Uterus volume reduction ($n = 41$)	6×10^{-6}	0.71	–0.93	0.90	−18.6	0.069
Fibroid volume reduction ($n = 39$)	2.3×10^{-5}	0.18	6.68	0.44	2.62	0.74
	Multivariate logistic regression: model odds ratio [95% CI]					
Model for symptoms						
Improvement in menorrhagia ($n = 32$)	1.01 [0.99–1.1]	0.051	0.41 [0.05–3.6]	0.41	0.82 [0.18–3.8]	0.79
Improvement in bulk related symptoms ($n = 42$)	1.001 [0.99–1.1]	0.98	0.5 [0.1–2.6]	0.50	0.52 [0.14–1.9]	0.32
Improvement in urinary symptoms ($n = 42$)	1.001 [1.0001–1.01]	0.047	0.73 [0.12–4.3]	0.73	1.1 [0.24–4.8]	0.91
Model for complications						
Vomiting ($n = 73$)	1.01 [0.99–1.1]	0.54	1.86 [0.55–6.30]	0.31	0.37 [0.13–1.09]	0.073
Fever ($n = 74$)	1.001 [0.99–1.1]	0.87	1.03 [0.33–3.28]	0.95	0.67 [0.23–1.91]	0.45
Pain ($n = 75$)	1.01 [0.99–1.1]	0.76	0.50 [0.14–1.84]	0.30	0.63 [0.21–1.87]	0.40
Expulsion ($n = 89$)	1.01 [0.99–1.1]	0.44	0.99 [0.26–3.73]	0.98	0.70 [0.21–2.26]	0.54

Note. CI, confidence interval

Discussion

UAE has been widely described as a safe and effective treatment for symptomatic uterine fibroids. The technical failure rate in this report was slightly higher than the 3–5% failure rates reported in many other studies ($p < 0.0001$) [12, 13]. The five cases of anatomical variation were not excessive compared to other studies; however, the procedural technique failed at a relatively high rate. This was due to the low proficiency of the radiologists during the first 6 months of the study.

The symptom improvement results reported here were similar to those published elsewhere [13, 14], though the mean age of our patients was lower than that reported in many other studies (36.09 vs. 42–44.2 years) [15, 16]. In The Fibroid Registry, Spies et al. confirmed that UAE results in symptom improvement for most patients [17]. There were no mortalities in this study, as expected, considering that major complications after embolization are rare [3, 5, 6, 9]. Approximately 30% of our patients experienced postprocedure pain, and pain is a common side effect of UAE for fibroids [18]. The specific cause of the pain after UAE has still not been identified with certainty, although the primary short-term pain is most likely the result of ischemia [18]. Although recent studies have stressed that better results are demonstrated with embolospheres compared to PVA, this study started 6 years ago and we used PVA from the beginning; thus we continued with this particle to prevent methodical biases.

Similar to our findings, Katsumori et al. [9] found that tumor size is not a risk factor in patients undergoing UAE for fibroids and the primary size of the fibroids did not affect the complication rate. In addition, neither our study nor the Katsumori study found a statistical difference between the baseline fibroid volume and the amount of reduction in fibroid size; however, we did not perform embolization in patients with fibroids larger than 2618 mL. In contrast to these findings, in the EMMY Trial, Volkers et al. found that a larger fibroid volume (>100 cm^3) was associated with an increased risk of complications [19]. Furthermore, several reports have found correlations between improvement in menorrhagia and primary tumor size [9, 17]. Spies and et al. reported that smaller baseline fibroid size was associated with a positive imaging outcome [20], and they mentioned that larger fibroid size tended to result in a net negative effect on the change in symptom score [17].

We found no statistical differences between location of the fibroids and reduction of symptoms, reduction in dominant fibroid size, or complication rate. In contrast, Zhou et al. found that submucosal and intramural fibroid locations have favorable effects on the therapeutic efficacy of UAE. However, they evaluated 32 symptomatic patients and followed them for only 6 months [21]. Rajan et al. found no association between the location of a dominant fibroid tumor and intrauterine infectious complications [22]. Spies et al. [17], in assessing some of the variables associated with UAE, concluded that a submucosal fibroid location was associated with a greater volume reduction after 3 months; however, after 12 months this association was abolished ($p = 0.9$), consistent with our results. Also, in contrast to our findings, Kroncke et al. [23] reported that the number of fibroids correlated ($p < 0.05$) with improvements in the amount of bleeding and pelvic pressure.

One limitation of our study was the quantity of missing data, and this problem became worse as the study progressed; this was particularly notable for imaging follow-ups. This may explain some of the differences found between our study and others, although similar limitations existed in other reports [20, 24].

Because there remain discrepancies between studies (e.g., the Katsumori study, our study, and the Fibroid Registry), further research is necessary for a more definitive evaluation of the effects of baseline fibroid volume, fibroid multiplicity, and fibroid location on the therapeutic efficacy of UAE.

In conclusion, UAE is an effective treatment for uterine fibroids, with few complications. In this study the size, location, and number of fibroids did not affect the success or the complication rate of UAE.

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