Uterine artery embolization versus myomectomy: a multicenter comparative study

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Objective: To determine whether there is significant quality of life score improvement after uterine artery embolization (UAE) and to compare UAE and myomectomy outcomes.
Design: Prospective cohort controlled study.
Setting: Sixteen medical centers in the United States.
Patient(s): One hundred forty-nine UAE patients and 60 myomectomy patients. Patients were assigned to myomectomy or UAE on the basis of a best treatment decision made by the patient and her physician. All patients were observed for 6 months. The UAE patients also had follow-up examinations at 1 year.
Intervention(s): Myomectomy or UAE.
Main Outcome Measure(s): Quality of life score changes, menstrual bleeding score changes, uterine size differences, time off, and adverse events.
Result(s): Both groups experienced statistically significant improvements in the uterine fibroid quality of life score, menstrual bleeding, uterine volume, and overall postoperative quality of life. The mean hospital stay was 1 day for the UAE patients, compared with 2.5 days for the myomectomy patients. The UAE and myomectomy patients returned to their normal activities in 15 days and 44 days, respectively, and returned to work in 10 days and 37 days, respectively. At least one adverse event occurred in 40.1% of the myomectomy patients, compared with 22.1% in the UAE group.
Conclusion(s): The uterine fibroid quality of life score was significantly improved in both groups. No significant differences were observed in bleeding improvement, uterine volume reduction, uterine fibroid quality of life score improvement, and overall quality of life score improvement between groups. Patients receiving UAE required fewer days off work, fewer hospital days, and experienced fewer adverse events. (Fertil Steril® 2006;85:14–21. ©2006 by American Society for Reproductive Medicine.)

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The uterine-sparing treatment of choice for symptomatic uterine fibroids has been myomectomy (1, 2). As an alternative, uterine artery embolization (UAE) for fibroids was introduced in 1995 in France by Ravina et al (3). Goodwin et al. (4) published the first U.S. experience 2 years later, confirming the French group's clinical success. Subsequently, various studies have shown that UAE is 80%–90% successful in improving symptoms (5–15). As of 1997, approximately 25,000–30,000 women with symptomatic fibroids had been treated with UAE worldwide (16).

More than 200 articles on fibroid embolization have been published, but many of these studies were not prospective or did not compare UAE outcomes against other established gynecologic procedures. The American College of Obstetrics and Gynecology has recently recognized UAE as an acceptable therapy, acknowledging that the procedure reduces fibroid size and improves menstrual bleeding, pelvic pain, and other symptoms, at least in the short term (17).

The data comparing myomectomy with UAE is limited to three retrospective studies (18–20). One of these (18) found that women who underwent embolization were more likely to need further invasive treatment. However, overall success rates were similar. Result from another study (19) supported the view that UAE is a less invasive technique that results in a shorter recovery time and the use of fewer postoperative narcotics.

Although there is great enthusiasm for a minimally invasive therapy that treats the symptoms of fibroid disease, a prospective randomized trial of UAE and myomectomy has been difficult to perform owing to lack of participant interest. To overcome this limitation, we designed a multicenter, nonrandomized cohort prospective trial to evaluate the differences between these two approaches. Here we report the results of this trial.

MATERIALS AND METHODS

The study took place at 16 sites in the United States. Institutional review board approval was obtained at each site, and all patients provided written informed consent. There were 149 UAE patients and 60 myomectomy "intention to treat" (ITT) patients in the study. Patients were assigned to myomectomy or UAE on the basis of a best treatment decision made by the patient and her physician according to the standard of care at each site. Six-month follow-up was completed for both groups, and 1-year follow-up was completed for the UAE group only.

The primary endpoint in the study was a ≥5-point improvement in the uterine fibroid quality of life questionnaire score (UFQoLs) (21) from baseline to postoperative month 6 in the UAE patients. The 5-point cutoff was chosen as a significant level by an expert panel of gynecologists and interventional radiologists before the start of the study. For the primary endpoint, the general agreement of the panel was that a UAE "success" rate (≥5-point increase at postoperative month 6 months for UFQoLs) of >75% was thought to be clinically meaningful. Assuming an 83% success rate for the UAE group on overall fibroid symptoms, with a sample size of 130 patients, the lower bound of a two-sided 95.0% exact confidence interval (CI) for a single proportion would be approximately 76% (95% CI 0.755–0.891). This sample size provided a 95% CI that was reasonably narrow and a lower bound that was above the limit of 75% that was thought to be a clinically meaningful UAE success rate.

Six-month secondary endpoints included comparison of change in UFQoLs between the myomectomy group and UAE group, adverse events (AEs), overall quality of life scores (QoLs), change in size of the dominant fibroid (UAE cohort only), uterine volume change, menstrual bleeding changes (22), hospitalization days, time to return to normal daily activities and work, and relationship between dominant fibroid size change and UFQoLs (UAE cohort only). One-year secondary endpoints for the UAE cohort only included UFQoLs, menstrual bleeding changes, AEs, recurrences, pregnancies, and fibroid treatments.

Inclusion criteria were age ≥30 years, symptoms severe enough to warrant therapy, regular menses, normal results on Papanicolaou smear, and the ability to complete the follow-up requirements. The diagnosis of uterine fibroids must have been confirmed with history, examination, and ultrasound or magnetic resonance imaging (MRI). Patients in the myomectomy group were also eligible if they had infertility related to fibroids.

Exclusion criteria included hysteroscopically resectable fibroids, pelvic infection, gynecologic malignancy, undiagnosed pelvic mass outside of the uterus, unexplained abnormal menstrual bleeding, infection, coagulopathy, history of pelvic irradiation, American Society of Anesthesiologists score ≥4 (23), FSH level >40 IU/L, or participation in any other investigational device or drug study. The UAE patients were also excluded if they wished to become pregnant in the future, had an abnormal serum creatinine level, uterine arteriovenous fistula, severe contrast allergy, or pedunculated subserosal fibroid (with attachment to uterus of <30% of the diameter of the fibroid).

All eligible patients were asked to complete the UFQoL questionnaire. Any patient with a score of ≥90 points on a scale of 0–100 (worst to best) was excluded unless she was planning to undergo myomectomy for infertility.

Preprocedural assessment included baseline UFQoLs, QoLs, history, symptom assessment, and imaging evaluation. Laboratory evaluation for the UAE cohort included measurement of creatinine and FSH levels and a pregnancy test. In the myomectomy cohort, laboratory evaluation included a pregnancy test and measurement of FSH and hemoglobin levels.

Patients underwent baseline MRI. Volumes were calculated with the formula for a prolate ellipse. Patients were prepared for either UAE or abdominal myomectomy accord-

TABLE 1

Fibroid symptom assessment

	UAE (n = 149)	Myomectomy (n = 60)	All patients (n = 209)	*P*
Dominant symptom				.02[a]
Abnormal bleeding	77 (51.7%)	20 (33.3%)	97 (46.4%)	
Bulk/pressure	38 (25.5%)	16 (26.7%)	54 (25.8%)	
Pelvic pain	29 (19.5%)	18 (30.0%)	47 (22.5%)	
Infertility	0 (0.0%)	2 (3.3%)	2 (1.0%)	
Other	5 (3.4%)	4 (6.7%)	9 (4.3%)	
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Duration of dominant symptom (mo)				.08[b]
No. of patients that provided duration of dominant symptom	145	60	205	
Mean	27.7	36.5	30.3	
SD	37.64	43.73	39.62	
Median	12.0	24.0	12.5	
Minimum	0.03	0.07	0.03	
Maximum	204	252	252	

[a] Chi-square test.
[b] Wilcoxon rank–sum test.

Goodwin. Uterine artery embolization vs. myomectomy. Fertil Steril 2006.

ing to each institution's standard procedures and practices (1, 3–15, 24). The UAE procedures were performed with polyvinyl alcohol particles (Contour Emboli PVA, Boston Scientific, Watertown, MA) and a microcatheter (FasTracker 325, Boston Scientific). Patient preparation, anesthesia and analgesia details, procedure information, and discharge information were recorded.

A Clinical Events Committee composed of three physicians who were independent of the clinical trial assisted in the interpretation of the clinical results including AEs and monitored the study groups' adherence to the entry criteria and protocol.

Adverse events were classified in accordance with established definitions and based on a modification to the Society of Interventional Radiology reporting standards (25). Events were classified as [1] not an event—event was not a discrete event; [2] minor event—event did not require therapy or result in any consequences, required nominal therapy, including observational overnight admission, or required treatment and/or hospitalization for ≤48 hours without sequelae; or [3] major event—major therapy or increase in care beyond 48 hours, permanent adverse sequelae, or death. Ovarian failure was defined as a new elevation in FSH levels with amenorrhea or hot flashes.

All statistical analyses were performed with SAS for Windows (version 8.00 or higher) (SAS Institute, Cary, NC). All statistical tests were two-sided unless otherwise stated, and $P=.05$ was considered statistically significant. Reported changes from baseline values were actual values and were not adjusted for any covariates. Logistic regression analyses were conducted with stepwise model selection. Interactions were assessed. The main model selection criteria used were Akaike Information Criterion and Schwartz Criterion Statistics. The primary analysis was performed according to the ITT principle. The ITT population was defined as all patients in whom the UAE or myomectomy was initiated.

RESULTS

The UAE patients were older (43.9 vs. 38.2 years, $P<.0001$), had more prior pregnancies (75.2% vs. 48.3%, $P<.0001$), more tubal ligations (18.1% vs. 1.7%, $P=.0005$), longer menstrual periods (7 vs. 6.2 days, $P=.02$), and were more likely to have bleeding as a presenting symptom (51.7% vs. 33.3%, $P=.02$). The myomectomy patients reported more musculoskeletal problems (23.3% vs. 7.4%, $P=.003$), miscellaneous pelvic and "other" abnormalities (8.3% vs. 1.3%, $P=.005$, and 18.3% vs. 7.4%, $P=.036$, respectively). Symptom and MRI assessment results are presented in Tables 1 and 2. Logistic regression demonstrated no significant impact of these differences on success rates ($P>.05$) (see success discussion below).

Of the 149 UAE patients, 143 (96.0%) received conscious sedation during the procedure. Of the 60 myomectomy patients, 59 (98.3%) were placed under general anesthesia during the procedure ($P<.0001$).

TABLE 2

MRI assessment

	UAE (n = 149)	Myomectomy (n = 60)	All patients (n = 209)	*P*
Number of fibroids present				.0001[a]
0	2 (1.3)[b]	1 (1.7)[c]	3 (1.4)	
1	9 (6.0)	5 (8.3)	14 (6.7)	
2	10 (6.7)	4 (6.7)	14 (6.7)	
3	10 (6.7)	8 (13.3)	18 (8.6)	
4	10 (6.7)	7 (11.7)	17 (8.1)	
5	6 (4.0)	2 (3.3)	8 (3.8)	
6–10	27 (18.1)	14 (23.3)	41 (19.6)	
>10	75 (50.3)	13 (21.7)	88 (42.1)	
Missing	0 (0.0)	6 (10.0)[d]	6 (2.9)	
Location of first dominant fibroid				<.0001[a]
Intramural	88 (59.1)	26 (43.3)	114 (54.5)	
Submucosal	1 (0.7)	3 (5.0)	4 (1.9)	
Submucosal pedunculated	17 (11.4)	2 (3.3)	19 (9.1)	
Sebserosal	8 (5.4)	8 (13.3)	16 (7.7)	
Subserosal pedunculated	31 (20.8)	13 (21.7)	44 (21.1)	
Other	0 (0.0)	1 (1.7)	1 (0.5)	
Cannot determine	2 (1.3)	0 (0.0)	2 (1.0)	
Missing	2 (1.3)	7 (11.7)[d]	9 (4.3)	
Size of dominant fibroid (cm^3)				.081[e]
n	147	53	200	
Mean	182.12	226.92	193.99	
SD	208.978	196.394	206.1861	
Median	114.72	185.75	130.62	
Minimum	0.63	6.45	0.63	
Maximum	1116.91	869.95	1116.91	
Uterine volume at baseline (cm^3)	658.4	590.6		>.05
Uterine volume at 3 mo (cm^3)	461.9 *P*<.001			
Uterine volume at 6 mo (cm^3)	404.3 *P*<.001	251 *P*<.001		>.05

Note: Data are presented as n (%), unless otherwise noted.

[a] Chi-square test.

[b] One UAE patient had an ultrasound examination at baseline that showed evidence of the presence of fibroids, before her enrollment and UAE procedure. A second UAE patient had a MRI examination at baseline that showed evidence of the presence of fibroids, before her enrollment and UAE procedure. Subsequent to enrollment and treatment, the Core Laboratory was unable to measure uterine fibroids for both patients after reviewing each patient's baseline MRI. The Core Laboratory noted the presence of adenomyosis.

[c] The Core Laboratory was unable to measure uterine fibroids for one myomectomy patient because the patient's baseline MRI was considered corrupt and could not be reviewed.

[d] Poor image quality (4), baseline not released by patient (1), incomplete examination (1), and corrupted file (1).

[e] Wilcoxon rank–sum test.

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Except for four patients, all of the myomectomy patients had all of their fibroids removed, and those that remained were small (<1 cm). Of the polyvinyl alcohol particles used in the study, 12.7% were 250–355 μm, 63.1% were 355–500 μm, and 24.1% were 500–710 μm. One hundred forty-seven UAE patients had successful bilateral embolizations. Two UAE technical failures occurred. One patient could not be catheterized because of a small, markedly tortuous uterine artery. The second patient had bilateral internal iliac artery occlusion secondary to prior surgery.

TABLE 3

Change from baseline, general quality of life assessments

	UAE 3 mo	UAE 6 mo	Myomectomy 3 mo	Myomectomy 6 mo
Higher score = higher functioning/less interference/less symptoms/less distress				
General health perception	4.1 (13.7)	4.3 (15.6)	6.0 (26.5)	12.2 (25.2)
Comprehensive health perception	44.6 (27.5)	44.4 (27.6)	46.8 (26.6)	42.6 (32.5)
Physical functioning	16.0 (28.2)	17.8 (25.3)	15.4 (27.7)	20.1 (29.2)
Difficulty with activity	22.1 (27.4)	26.8 (25.7)	20.8 (26.9)	25.0 (30.4)
Sleep	18.1 (19.6)	20.8 (21.2)	14.9 (18.0)	15.6 (18.6)
Mental health	12.7 (17.1)	14.9 (18.3)	11.5 (15.4)	13.9 (20.9)
Energy/vitality	24.9 (20.8)	26.9 (22.7)	23.7 (20.4)	26.3 (23.0)
Self image	29.0 (22.9)	30.2 (24.4)	27.7 (31.7)	36.2 (29.2)
Sexual functioning	8.0 (22.7)	11.3 (24.7)	15.4 (19.1)	15.6 (25.2)
Higher score = lower functioning/more interference/more symptoms/more distress				
Restricted activity 1[a]	−8.4 (8.5)	−9.4 (8.8)	−6.6 (12.2)	−9.6 (10.6)
Restricted activity 2[b]	−1.1 (3.7)	−1.7 (3.1)	−1.1 (5.0)	−1.8 (5.0)
Restricted activity 3[c]	−4.9 (7.5)	−5.2 (7.5)	−2.2 (9.0)	−4.2 (7.4)
Pain	−21.5 (23.1)	−27.7 (25.7)	−28.7 (26.6)	−28.7 (26.8)
Health Distress	−26.5 (25.0)	−29.4 (24.9)	−25.4 (25.0)	−26.1 (27.7)

Data are presented as mean (SD). $P>.05$ for all measures (Wilcoxon rank–sum test).

[a] How many days did you feel less well than usual because of your fibroids?

[b] How many days did you stay in bed more than half the day because of the fibroids?

[c] How many days did you cut down on your usual activities more than half the day because of your fibroids?

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Of the 149 patients in the UAE group, 8 achieved a ≤5-point increase in the UFQoLs at 6 months, 2 were technical failures, 10 were lost to follow-up, 4 withdrew consent, 1 had a postprocedure myomectomy, 2 had a postprocedure hysterectomy (1 for therapy failure and 1 for growing adnexal mass), and 1 was excluded from the analysis because of a significant inclusion criteria protocol deviation (FSH level >40 IU/L). Thus, UAE was not considered successful in 28 patients (success in 81.2%).

Of the 60 patients in the myomectomy group, 5 achieved a ≤5-point increase on the UFQoLs at 6 months, 1 required a hysterectomy (converted at time of myomectomy), 3 were lost to follow-up, 1 withdrew consent, 3 had incomplete UFQoLs, and 2 were eliminated secondary to protocol deviations. Thus, myomectomy was not considered successful in 15 patients (success in 75%). The mean difference in success as discussed above between the UAE and myomectomy arms at 6 months was 6.21% ($P>.05$).

As shown in Table 3, overall QoLs for both groups at 6 months improved significantly. There were no statistically significant differences between the two groups.

The UAE cohort experienced a reduction in mean menstrual bleeding scores (Ruta scale) of 49.2% at 3 months ($P<.001$) and of 55.2% at 6 months after the procedure ($P<.001$). The myomectomy cohort experienced a reduction in mean menstrual bleeding scores of 43.0% at 3 months ($P<.001$) and of 46.1% at 6 months after the procedure ($P<.001$). There was no statistically significant difference in reduction in mean menstrual bleeding scores between the two groups ($P>.05$). These results are shown Table 4.

The mean duration of hospital stay for the UAE patients was 23.8 hours, compared with 61.6 hours for the myomectomy group ($P<.0001$). The mean number of days for the UAE cohort to return to normal activities (reflects return to complete physical health) was 14.6 days, compared with 44.4 days for the myomectomy cohort ($P<.05$). The mean number of missed workdays for the UAE cohort was 9.9 days, compared with 37.0 days for the myomectomy cohort ($P<.001$).

Of the 149 UAE patients, 33 (22.1%) experienced at least 1 AE, compared with 24 (40%) of the 60 myomectomy patients ($P=0.01$). There were a total of 53 AEs in the UAE group and 43 AEs in the myomectomy group. The AEs were

TABLE 4

Menorrhagia questionnaire bleeding scores

	UAE							Myomectomy						
	n	Mean	SD	Minimum	Maximum	% Change	P	n	Mean	SD	Minimum	Maximum	% Change	P
Menorrhagia score														
Baseline	149	46.2	15.6	12.8	85.7			57	45.6	18.7	14.3	81.6		
3 mo	138	21.5	11.9	5.1	63.2			54	22.5	11.5	8.6	81.6		
6 mo	128	18.4	10.1	2.6	64.3			53	21.4	11.8	7.7	66.7		
1 y	113	16.7	10.2	2.6	53.8									
Bleeding score changes														
3 mo	138	−24.5	16.7	−63.7	20.3	−49.2	<.001	55	−22.8	19.0	−68.3	17.3	−43.0	<.001
6 mo	128	−26.6	15.9	−65.8	11.5	−55.2	<.001	54	−24.1	18.8	−70.9	9.6	−46.1	<.001
1 year	113	−28.6	15.1	−65.0	3.3	−61.1	<.001							

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related to the procedure in 24 (45.3%) of the 53 events in the UAE group and in 22 (51.2%) of the 43 events in the myomectomy group. Related UAE AEs included 4 urinary tract infections (UTIs), 3 prolapsed fibroids, 4 postembolization syndromes, 2 vaginal discharges, 2 hematomas, 2 excessive pains, and 7 others. Myomectomy-related AEs included 5 UTIs, 5 hemorrhages, 1 surgical injury to organs, 1 allergic reaction, 1 urinary retention, 1 wound infection, 1 adverse drug reaction, 1 constipation, and 6 others. Two of the UAE patients had transient ovarian dysfunction, but no patient had permanent ovarian failure. There were no reports of device-related AEs in the UAE cohort.

There were six major AEs in the UAE cohort, including ruptured appendix, adnexal mass, vaginal discharge, abdominal cramping, and two postembolization syndrome, and one in the myomectomy cohort (hemorrhage) ($P>.05$). Of the six major AEs in the UAE cohort, three were procedure related, one not procedure related, and two were classified as new onset or prior condition. The one major AE in the myomectomy cohort was classified as procedure related.

At baseline, the UAE group had a greater number of fibroids per patient. Logistic regression showed no effect of this difference on success ($P>.05$). The size of the dominant fibroid was not significantly different in the two groups. These results are listed in Table 2.

At baseline, the UAE group's mean uterine volume was 658.4 cm^3. In the myomectomy group the volume was 590.6 cm^3. The UAE cohort experienced a reduction in mean total uterine volume of 30% (down to 461.9 cm^3) at 3 months ($P<.001$) and 38.6% (down to 404.3 cm^3) at 6 months after the procedure ($P<.001$). The myomectomy cohort experienced a reduction in mean total uterine volume of 57.5% (down to 251 cm^3) at 6 months after the procedure ($P<.001$). The difference between the cohorts was not significantly different ($P>.05$). These results are shown in Table 2. For comparison purposes, the uterus is approximately 220 cm^3 normally, 400 cm^3 at 10 weeks, and 800 cm^3 at 12 weeks.

The UAE cohort experienced a mean dominant fibroid size reduction of 37.7% at 3 months ($P<.05$) and 53.9% at 6 months after the procedure ($P<.05$). The correlations coefficient between change in dominant fibroid size and UFQoLs at 6 months for the UAE cohort was 0.006 ($P=.948$). Therefore there was no statistically significant correlation between change in dominant fibroid size and UFQoLs improvement.

At 1 year, 120 of 149 UAE patients were available for follow-up. Eighty-seven percent (105 of 120) did not have any recurrence or new fibroid symptoms, and only 1.7% (2 of 120) had sought additional fibroid therapy, and in both cases the therapy was pharmaceutical. No additional UAE-related complications were reported. No pregnancies were reported. All UFQoLs measures showed statistically significant improvement as compared with baseline, except for hot flashes. Bleeding scores continued to improve, as shown in Table 4.

DISCUSSION

Overall, we found that both the UAE and myomectomy groups experienced similar and statistically significant improvements in UFQoLs, menstrual bleeding, and uterine volume at 6 months. The UAE results showed durability at 1 year of follow-up. The UAE patients did not require general anesthesia, returned to normal activities earlier, required fewer days in hospital and off work, and had fewer AEs.

Eighty-one percent of the UAE patients and 75% of the myomectomy patients had a successful outcome at 6 months. This difference was not statistically significant. These results mirror those of Broder et al. (18), who also found no significant difference in overall success.

Unlike previous articles (7–13, 26) that reported only the percentage of patients who experienced significant reductions in bleeding after UAE and myomectomy, we quantified the reduction in bleeding. One article (27) has called for researchers to quantify outcomes. One unexpected drawback is that it will be difficult to compare our quantified results with the more subjective and qualitative results contained in earlier publications.

In our study, the volume of the uterus in the UAE group decreased by a mean of 38.6%, similar to what has been previously reported (7–9). Why this was so was not clear from our analyses. In the myomectomy group, the mean reduction at 6 months was 57.5%, which is comparable to the 49.9% 3–6-month reduction reported by Beyth et al. (28).

The difference between the average hospital stay for the UAE and myomectomy patients was statistically significant, as was the recovery time needed to return to activities of daily living and work. Recovery times were shorter for the UAE patients. This confirms earlier reports wherein these types of differences were also noted (19, 29).

The occurrence of at least one AE was more common in the myomectomy group. The types of complications that occurred are consistent with prior reports. Of note, two UAE patients experienced transient ovarian dysfunction, which might have been related to nontarget embolization of the ovaries (30). None of the patients in either group experienced permanent ovarian failure. Ovarian failure after UAE is age related, occurring most often in women aged >45 years (15). Women aged <40 years are affected uncommonly, and ovarian failure after UAE in women aged <35 years is rare (15).

Uterine artery technical failures were rare, occurring in only two patients. This is consistent with previous reports, in which the technical success rates have all exceeded 95% (3–15, 31).

Our UAE patients differed from the myomectomy patients in several areas. The UAE patients were older. Younger age has been associated with a higher rate of clinical failure in patients undergoing uterine embolization (9). Patients who present at a younger age might have more aggressive disease. In addition, for the younger patient there is more time after treatment and before menopause for fibroids to regrow. Thus, a possible bias in favor of the UAE group should at least be considered. Statistical analysis did not reveal any such effect.

In most of our UAE patients, bleeding was the main symptom, whereas most of the myomectomy patients reported bulk symptoms, pain, and/or infertility. Previous studies have shown that patients undergoing embolization for bleeding might have a better outcome than patients with pain or bulk symptoms (12, 32). This difference might have skewed our results in favor of the UAE group. On the other hand, Razavi et al. (19) found that the results in their myomectomy patients were superior to those in their UAE patients with mass effect, which might have possibly skewed the overall success rates in favor of the myomectomy group.

The UAE patients had more fibroids. This probably reflected preselection bias. The number of fibroids has been associated with worse outcomes in myomectomy patients but has not been shown to be relevant in embolization patients (33, 34). This might have skewed the overall results in favor of the myomectomy group. Most of the myomectomy patients had all of their fibroids removed, and those that remained were small. This would also be expected to contribute to the level of success in the myomectomy group.

In our study, we used a nonrandomized design. Although the ideal study would be a prospective randomized controlled (RCT) trial, three groups of researchers in North America have attempted to conduct such a study unsuccessfully. Once patients were fully informed of their options, they were generally unwilling to be randomized (35; personal communications from L. Machan and N. Patel). European investigators have met with more success. A UAE vs. hysterectomy RCT conducted in Spain has been reported (36), although not all patients in the study were informed that they were being randomized. There is a UAE vs. hysterectomy RCT underway in the Netherlands (mentioned in Lumsden [37]) and a UAE vs. myomectomy or hysterectomy RCT in progress in Scotland (mentioned in Lumsden [37]).

In summary, our data show that UAE is as effective as myomectomy in treating symptomatic fibroids but offers the advantages of a speedier and less-eventful recovery.

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