



Leiomyoma Infarction after Uterine Artery Embolization: Influence of Embolic Agent and Leiomyoma Size and Location on Outcome

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ABSTRACT

Purpose: To study the factors that might impact infarction of individual uterine leiomyomas and total tumor burden after uterine artery embolization (UAE).

Materials and Methods: This retrospective study included 91 patients (mean age, 44 y [range, 34–54 y]) who underwent UAE with tris-acryl gelatin microspheres (TAGMs) or nonspherical polyvinyl alcohol (PVA) particles. Twenty-one patients were treated with PVA (23%) and 70 were treated with TAGMs (77%). A total of 356 uterine leiomyomas were assessed, with a median uterine volume of 533 cm³ (range, 321–848 cm³). A reader masked to demographic and technical details reviewed contrast-enhanced magnetic resonance images before and 3 months after UAE to estimate the extent of tumor infarction.

Results: There was no significant difference in global or individual tumor infarction rate between embolizations with TAGMs and PVA particles ($P = .73$ and $P = .3$, respectively). Global infarction was not affected by age ($P = .53$), race ($P = .12$), number of leiomyomas ($P = .72$), or uterine volume ($P = .74$). Leiomyoma size did not influence individual tumor infarction ($P = .41$). Leiomyoma location was the sole factor that influenced individual tumor infarction rates, with pedunculated serosal tumors significantly less likely to show complete infarction than transmural tumors (odds ratio, 0.24; $P = .01$).

Conclusions: Nonspherical PVA particles and TAGMs produce similar rates of uterine leiomyoma infarction. Complete infarction of individual tumors is less likely in serosal and pedunculated serosal tumors.

ABBREVIATIONS

OR = odds ratio, PVA = polyvinyl alcohol, TAGM = tris-acryl gelatin microsphere, UAE = uterine artery embolization

Uterine artery embolization (UAE) has been extensively studied since its introduction for the treatment of symptomatic leiomyomas (1). Observational studies and randomized trials have demonstrated that UAE provides

symptomatic relief similar to hysterectomy (2–4). This procedure is accepted as an alternative to hysterectomy, and the American College of Obstetricians and Gynecologists has recognized the procedure as “safe and effective” (5).

Despite the procedure’s success, it does not always provide symptom control, and some women experience recurrence and require subsequent intervention (3,4). Among the factors that have been shown to affect the outcome of UAE, a large uterus and incomplete leiomyoma infarction have been associated with poorer outcomes (6–9). In contradistinction, other factors have been associated with positive outcomes after UAE, such as menorrhagia as a presenting symptom, multiple tumors, submucosal tumor location, and smaller tumor size (10).

Previous studies assessing the relative effectiveness of different embolic materials have suggested that these may also impact UAE outcomes. An early randomized trial (11)

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comparing tris-acryl gelatin microspheres (TAGMs; Embosphere Microspheres; Merit Medical, South Jordan, Utah) and nonspherical polyvinyl alcohol (PVA) particles (Contour; Boston Scientific, Marlborough, Massachusetts) showed no difference in global infarction of leiomyomas. A second study (12) showed that spherical PVA particles (Contour SE; Boston Scientific) were significantly less likely to cause tumor infarction compared with TAGMs. However, these studies focused on the overall tumor infarction rate, assessing the entire group of tumors in any single patient.

As part of an overall evaluation of UAE outcomes, previous studies have assessed the impact of tumor volume and location on the degree of volume reduction in individual uterine leiomyomas (13). However, the outcome studied was purely volume reduction of tumors over 1 year, as opposed to tumor infarction. Given that infarction precedes the change in volume and may have a better correlation with long-term outcome after UAE, the infarction of individual leiomyomas may be more relevant to study than the amount of shrinkage (14–16). Kroencke et al (17) showed a correlation between greater infarction on magnetic resonance (MR) imaging and decreased symptoms and repeat interventions. Overall, however, there has been relatively little study of the factors that impact the infarction rate of individual leiomyomas, specifically their size and location.

The present study was designed to analyze factors that might impact the likelihood of tumor infarction after UAE, including a range of demographic and anatomic factors that might influence outcomes.

MATERIALS AND METHODS

The present study was a retrospective review of existing records and images, and was approved by the institutional review board. The study was in compliance with the Health Insurance Portability and Accountability Act.

Patient Selection

Patients were selected between 2002 and 2004 and supplemented with additional patients treated from 2009 to 2011. This included all patients who had pre- and postprocedural imaging. Patients were premenopausal women 34–54 years of age with symptomatic leiomyomas. Patients were eligible if they underwent UAE for symptomatic leiomyomas, had a baseline contrast-enhanced MR examination at our institution, were not interested in future pregnancy, and did not have ongoing pelvic infections or other conditions that would preclude participation. Patients were also required to have a 3-month follow-up post-UAE MR imaging study at our institution for technical uniformity to facilitate comparison. Patients were excluded from the study if they did not have complete pre- and postprocedural MR imaging studies. A total of 91 patients and 356 individual leiomyomas were evaluated. Baseline patient characteristics of the cohort are presented in [Table 1](#).

Table 1. Baseline Characteristics and Embolic Agent Choice (N = 91)

Characteristic	Value
Mean age (y) ± SD	44 ± 4
Race	
White	28 (30.8)
Black	47 (51.7)
Asian	2 (2.2)
Asian-American	2 (2.2)
Hispanic	2 (2.2)
Other	3 (3.3)
Unknown	7 (7.7)
Uterine volume (cm ³)	
Median	533
IQR	321–848
Embolic agent	
PVA	21 (23.1)
TAGMs	70 (76.9)
No. of leiomyomas	
1	13 (14.3)
2–5	35 (38.5)
6–10	20 (22.0)
> 10	23 (25.3)

Note—Values in parentheses are percentages.

IQR = interquartile range; PVA = polyvinyl alcohol; SD = standard deviation; TAGM = tris-acryl gelatin microsphere.

Procedure

UAE was performed with bilateral embolization and bilateral femoral access with 5-F catheters and coaxial 3-F microcatheters (Renegade Hi-Flow; Boston Scientific) in each case. The embolic material used was TAGMs or nonspherical PVA particles based on operator preference. TAGMs were used in patients with small uteri (smaller than 14-wk size), and nonspherical PVA particles were used in larger uteri (larger than 14-wk size), particularly in patients with high uterine artery flow rates.

All procedures were performed by one of two experienced interventional radiologists, each with greater than 5 years of experience. Regardless of type, embolic material was prepared by the same method. Each vial of embolic material was mixed to a final volume 20 mL, with 10 mL of normal saline solution and 10 mL of nonionic contrast material (various manufacturers). For TAGMs, 500–700- μ m sizes were initially used, and, after a total of two vials were used in any vessel (4 mL embolic agent), the particle size was increased to 700–900 μ m and embolization was continued until completion. For nonspherical PVA, 355–500- μ m particles were used in all cases, with no increase in embolic particle size.

The endpoint of embolization for TAGMs was sluggish forward flow, defined by contrast material still visible in the main transverse or ascending uterine artery for five cardiac beats after the injection of 2 mL of contrast material. This corresponds to an angiographic image of continued patency of the main uterine artery and the proximal portions of its main

Table 2. Leiomyoma Location and Definition

Location	Description
Intracavitary	Pedunculated leiomyoma located completely within uterine cavity
Submucosal	Leiomyoma centered at endometrial/myometrial interface but not intracavitary
Intramural/submucosal	Leiomyoma that originates in central myometrium and extends to endometrium
Intramural	Leiomyoma that originates in central myometrium but does not extend to endometrium or serosa
Transmural	Leiomyoma that extends through entire uterine wall, from endometrial lining to serosa
Intramural/subserosal	Leiomyoma that originates in central myometrium and extends to uterine serosa
Subserosal	Leiomyoma centered beneath serosa of uterus with expansion of serosa but no extension beyond serosa
Pedunculated subserosal	Leiomyoma that arises at serosal surface and is entirely beyond uterine margin
Pedunculated cervical	Leiomyoma originates from cervical margin but extends beyond that margin

Table 3. Analysis of Global Leiomyoma Infarction (N = 91)

Variable	No. of Pts.	Median Global Infarction (IQR)	P Value
Race			.11*
Black	47	95 (90–100)	
White	28	97 (95–100)	
Other	16	100 (97–100)	
No. of leiomyomas			.71*
1	13	100 (95–100)	
2–5	35	95 (90–100)	
6–10	20	95 (90–100)	
> 10	23	98 (95–100)	
Embollic agent			.73 [†]
PVA	21	98 (90–100)	
TAGMs	70	97 (90–100)	
		Spearman Correlation Coefficient	
Age		0.06598	.53
Uterine volume (cm ³)		–0.03466	.74

IQR = interquartile range; PVA = polyvinyl alcohol; TAGM = tris-acryl gelatin microsphere.

*Nonparametric Kruskal–Wallis test.

[†]Two-sample Wilcoxon test.

branches, with no continued perfusion of the contrast material to the leiomyomas (11). For nonspherical PVA particles, the occlusion was more complete, with an endpoint of near-stasis defined by the uterine artery still being visualized for 10 cardiac beats or longer after contrast material injection in the main uterine arteries. This endpoint corresponded to an angiographic image of a patent uterine artery, but with all of its distal branches completely occluded (11).

Table 4. Analysis of Individual Leiomyoma Infarction

Characteristic	No. Infarcted	Comparison vs. Transmural	
		OR (95% CI)	P Value
Overall success	265/356 (74.4)	–	–
Location and success of infarction			
Intracavitary	8/10 (80)	0.759 (0.151–3.80)	.79
Submucosal	33/40 (82.5)	0.984 (0.245–3.95)	.98
Intramural/submucosal	31/35 (88.5)	1.407 (0.406–4.87)	.59
Intramural	87/102 (85.3)	1.142 (0.365–3.57)	.81
Transmural	27/33 (81.8)	–	–
Intramural/subserosal	16/26 (61.5)	0.349 (0.096–1.27)	.11
Subserosal	37/59 (62.7)	0.348 (0.110–1.1)	.07
Pedunculated serosal*	26/51 (51)	0.244 (0.080–0.74)	.01
Total	265 (74.4)	–	–
Embollic agent			
PVA	192/263 (73)	–	–
TAGMs	73/93 (78.5)	–	–
PVA vs TAGMs	–	0.716 (0.376–1.36)	.3
Tumor size	–	0.956 (0.857–1.06)	.41

Note—Values in parentheses are percentages unless specified otherwise.

CI = confidence interval; OR = odds ratio; PVA = polyvinyl alcohol; TAGM = tris-acryl gelatin microsphere.

*Includes one case of pedunculated cervical.

Ovarian supply was assessed by preprocedural MR angiography or aortography at the time of the procedure. Patients found to have enlarged ovarian arteries underwent subsequent embolization if indicated.

Postprocedural Care

Upon completion of the procedure, each patient received postprocedural care as described previously (12). Patients received nonsteroidal antiinflammatory medication, parenteral narcotic agents via patient-controlled analgesia pump, and antiemetic medication as needed. After discharge, oral analgesic agents and antiemetic medications were provided. Each patient was seen at follow-up 3 months after treatment and also underwent a second MR examination with and without contrast medium at that time.

Data Collection and Analysis

The following information was obtained for each patient before UAE: age, ethnicity, volume of the uterus (in cubic centimeters), greatest diameter of the largest leiomyoma (in centimeters), number of leiomyomas, and location of leiomyomas. Volume of the uterus was calculated by using the formula for a prolate ellipse as described by

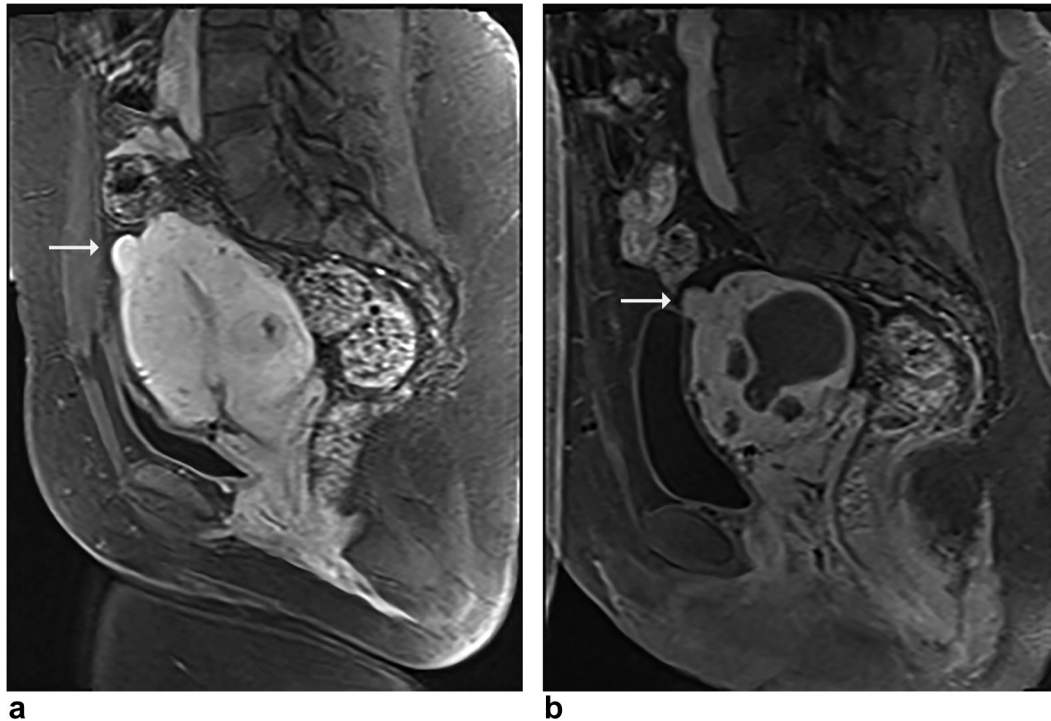


Figure 1. (a) T1-weighted sagittal contrast-enhanced MR image through the pelvis before UAE shows a small subserosal uterine leiomyoma (arrow). (b) T1-weighted sagittal contrast-enhanced MR image through the pelvis after treatment shows a small subserosal uterine leiomyoma (arrow) with no significant change in enhancement pattern (0% infarction).

Orsini et al (18). Patients with greater than five leiomyomas were classified as having six to 10 leiomyomas or greater than 10 leiomyomas.

On the baseline MR imaging study, a maximum of five leiomyomas were chosen from each patient for individual analysis. Reviewers attempted to randomly choose a variety of sizes and locations for patients with more than five leiomyomas. If there were five or fewer leiomyomas, all leiomyomas were individually analyzed. Locations of leiomyomas were categorized as defined in Table 2, and the diameters of these tumors were recorded.

Contrast-enhanced MR imaging was performed 3 months after UAE with the same technique as the baseline study per previously described protocol (7). A single radiologist with greater than 20 years of experience in evaluating post-procedural MR images, who was blinded to patient cohort and embolic agent used, analyzed the extent of infarction of individual leiomyomas. Any leiomyoma identified on contrast-enhanced MR imaging after embolization that was not completely infarcted was then retroactively reviewed again at baseline, and its size and location were recorded. This was to ensure that all noninfarcted leiomyomas were included in the analysis. As a result, a few patients included in the study had more than five individual leiomyomas analyzed.

A global leiomyoma infarction percentage, defined as the estimate of complete infarction of all leiomyomas taken together and rounded to the nearest 5%, was assessed for each patient. Global infarction was defined as infarction of

all physical leiomyomas as defined by nonenhancement as a result of embolization. The success of infarction of individual leiomyomas was evaluated dichotomously as “complete” or “incomplete.” Complete infarction of individual leiomyomas was defined as zero perfusion of the tumor on follow-up contrast-enhanced MR imaging.

Data are presented as mean and standard deviation for continuous measures or median and interquartile range for skewed variables. Frequencies and percentages are reported for categorical variables. Spearman correlation coefficient is reported for association of continuous variables with skewed global percentage infarction. Nonparametric methods—a two-sample Wilcoxon test or Kruskal–Wallis test—were used to compare global percentage infarction among categories of a categorical variable. Logistic regression with repeated measures is used to calculate odds ratios (ORs) and 95% confidence intervals of individual leiomyoma success.

RESULTS

All 91 patients had successful bilateral embolization, and one patient also had a single ovarian artery embolized to treat leiomyoma supply from that vessel. There were no complications recorded during hospitalization or at the time of imaging or clinical follow-up at 3 months.

Demographic summary statistics are provided in Table 1. The mean age was 44 years (range, 35–54 y), with black women comprising 52% of patients and white women

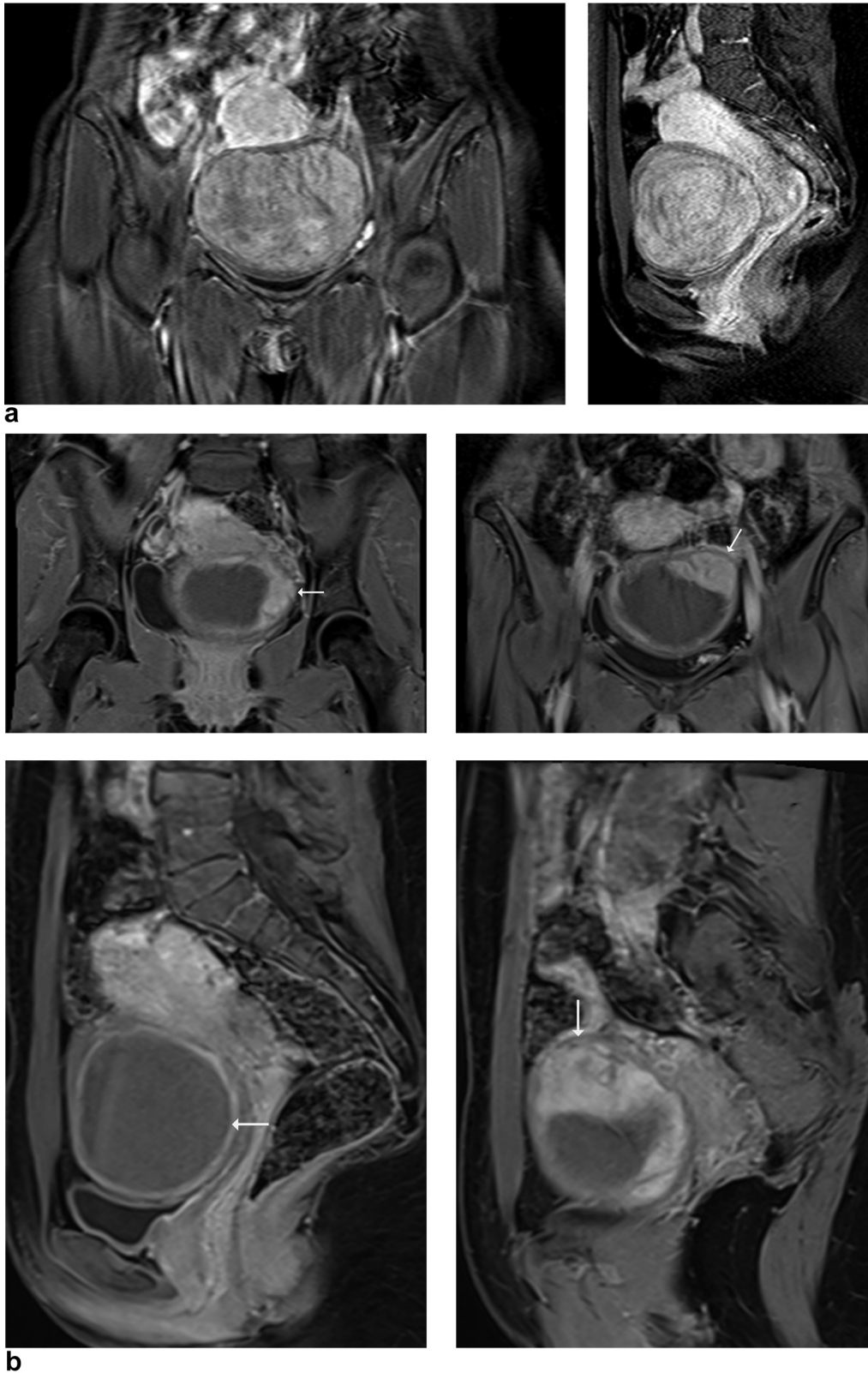


Figure 2. (a) T1-weighted coronal and sagittal contrast-enhanced MR images through the pelvis before UAE show a broad-based, pedunculated serosal leiomyoma. (b) T1-weighted coronal and sagittal contrast-enhanced MR images through the pelvis. Three-dimensional evaluation was performed of these leiomyomas in multiple planes and demonstrated partial infarction of approximately 80% (approximately 20% noninfarcted leiomyoma; white arrows).

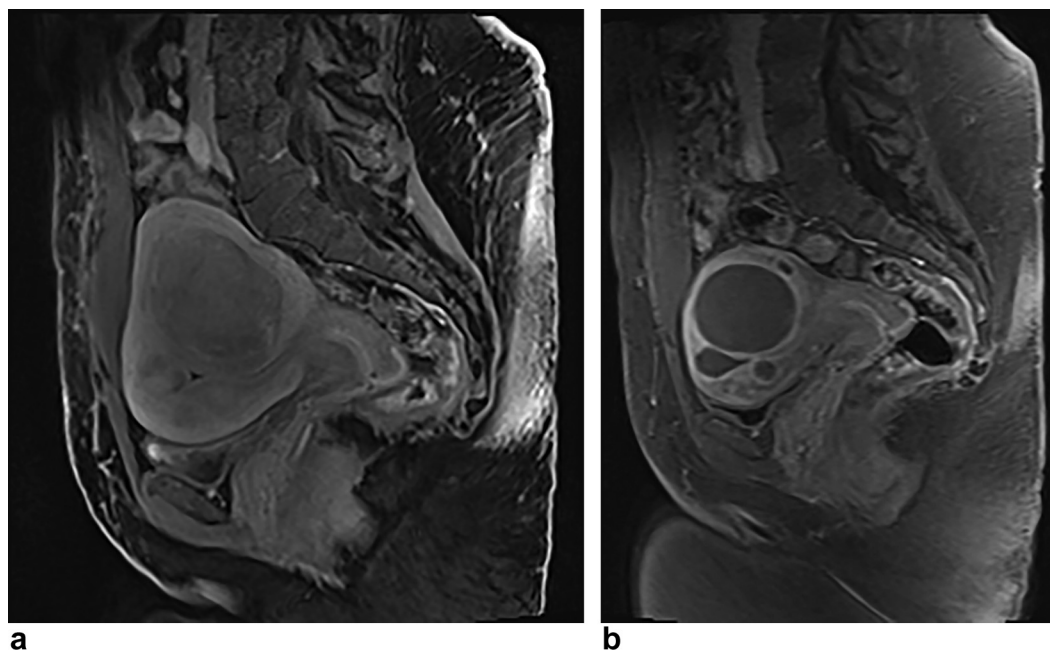


Figure 3. (a) T1-weighted sagittal contrast-enhanced MR image through the pelvis before UAE shows a large transmurular uterine leiomyoma. (b) T1-weighted sagittal contrast-enhanced MR image through the pelvis after UAE shows no enhancement of this leiomyoma, corresponding to 100% infarction.

31%. Median uterine volume was 533 cm³ (interquartile range, 321–848 cm³). The majority of patients were treated with TAGMs (76%) and most commonly had between two and five leiomyomas (35%).

Results of the analysis of global infarction rates are presented in **Table 3**. Global infarction was not affected by age ($P = .53$), race ($P = .12$), number of leiomyomas ($P = .72$), or uterine volume ($P = .74$). It was not affected by the embolic material used, with no difference detected between TAGMs and nonspheroidal PVA particles ($P = .73$).

The results of the analysis of individual leiomyoma infarction are presented in **Table 4**. Among all leiomyomas, 74% were completely infarcted successfully. This was not influenced by embolic agent used ($P = .3$) or tumor size ($P = .41$). Most of the leiomyoma locations had infarction rates in the 80%–90% range, with only serosal and pedunculated serosal leiomyomas having lower rates of infarction (**Figs 1–3**). The results of the logistic regression of leiomyoma location, using transmural location as the standard, demonstrated that pedunculated serosal leiomyomas had an OR for complete infarction of 0.24 ($P = .01$), the only location in which a significant difference was noted. There was a trend toward lower likelihood of infarction for serosal leiomyomas (OR, 0.35; 95% confidence interval, 0.11–1.1), but this was not statistically significant ($P = .07$).

DISCUSSION

Pelage's early work (7) established that leiomyoma infarction is a key component of long-term outcome of UAE.

Kroencke et al (17) subsequently showed that patients with completely infarcted leiomyomas experience improved outcomes and a decrease in future interventions. Toor et al (19) suggested that patients who show a suboptimal clinical response tend to have poor uterine and/or leiomyoma volume reduction. However, none of these studies investigated infarction of individual leiomyomas.

The present study found that patient age did not impact global infarction rates, which differs from the findings of other studies. Jha et al (20) found that increasing age correlated with decreased volume reduction in leiomyomas. In a different study by the same group (21), analysis found that age did not influence leiomyoma volume change. In a more recent study, Koesters et al (22) found that younger patient age and incomplete leiomyoma infarction led to higher rates of treatment failure. The present study supports the conclusion that age does not affect the success of infarction, but, given the differing outcomes reported earlier, this question is not settled.

Previous research has suggested a correlation between increased baseline uterine size and poorer clinical outcomes (23). The present study did not find any correlation between baseline uterine size and success of embolization from an imaging perspective, although the mean uterine volume in our cohort was not large (612 cm³). Inclusion of patients with much larger uteri might have affected infarction rates.

One of the primary findings of the present study is the confirmation that the two embolic materials studied perform similarly. The present study confirmed no difference in global infarction rates and no difference in individual infarction based on the embolic material used. Therefore,

the embolic agent can be chosen based on other factors, such as cost, operator preference, and ease of use.

Previous studies observed that location of leiomyomas also affects outcome after UAE. Specifically, submucosal leiomyomas are more likely to undergo a significant change in volume, which correlates with improved clinical outcome (10,21). A more recent study by Naguib et al (13) confirmed that the location of the leiomyoma correlates with the change in volume after UAE, again with submucosal leiomyomas showing greater volume reduction at follow-up. Toor et al (19) demonstrated that pedunculated subserosal leiomyomas were less likely to show a volume reduction in patients with poor clinical outcome. However, none of these studies specifically evaluated the extent of leiomyoma infarction as a potential cause.

The present study found that location of the individual leiomyomas affects the success of infarction, with pedunculated serosal leiomyomas less likely to undergo infarction compared with transmural leiomyomas; there was a failure to achieve complete infarction of approximately half of these tumors. In contradistinction, Smeets et al (24) found adequate infarction of pedunculated leiomyomas, but that study did not compare those results with those in transmural leiomyomas and included only leiomyomas 4 cm in diameter or greater. The present study included leiomyomas of all sizes, including very small ones. In this location, leiomyoma size might affect overall outcome, although, for our group as a whole, the baseline size of uterine leiomyomas (measured as greatest diameter of the leiomyoma in centimeters) did not significantly affect the success of embolization.

The present study has limitations. It is a retrospective analysis performed by one image reviewer. The patients in the cohort were limited to those with complete imaging, which may have biased the results. If a patient was found to have more than five leiomyomas, we did not include the additional leiomyomas beyond the five selected, which could have created selection bias, as not every leiomyoma was reviewed. However, leiomyomas were selected before review of patient outcomes. Also, the total number of participants ($N = 91$) is not large, and inclusion of a larger number of patients may have increased the strength of our conclusions.

Clinical outcomes of patients were intentionally not evaluated in the present study, as this has been extensively studied previously (2–4). The main interest was in focusing on leiomyoma infarction and the factors that might affect it, as this may be the best predictor of the risk of recurrence in the medium to long term.

In conclusion, the present study found that nonspherical PVA particles and TAGMs produce similar rates of individual leiomyoma infarction after UAE. The only factor that consistently impacted leiomyoma infarction was tumor location, with those on the outer margin of the uterus much less likely to show complete infarction than those deeper in the uterus. These findings may be of help in counseling

patients, particularly those with dominant serosal leiomyomas, as to the potential for incomplete treatment of tumors in this location.

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