Currently Available Embolics for Uterine Fibroid Embolization

A review of embolic agents used for uterine fibroid embolization in the United States, with tips and tricks for performing the procedure.

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Uterine fibroids (leiomyoma) are the most common pelvic tumor in women.[1-3] Fibroids are found in more than 70% of women by the onset of menopause; however, approximately 25% of women have symptoms severe enough to seek treatment.[4] Women most commonly present with heavy periods, painful menstrual cycles, or bulk symptoms. Fibroids are responsible for approximately 29% of gynecologic hospitalizations and 40% to 60% of hysterectomies.[5,6] Uterine fibroid embolization (UFE) was first described in 1995 by Ravina et al.[7] Since then, it has been extensively studied with multiple randomized controlled trials comparing UFE to surgery.[8-14] This repeatedly showed equivalent patient satisfaction and quality-of-life (QOL) outcomes, which led the American College of Obstetricians and Gynecologists to recognize UFE as a safe and effective alternative to hysterectomy.[15]

CURRENTLY APPLICABLE EMBOLIC MATERIALS

Fibroids are hypervascular tumors that increase blood supply to the fibroids as well as the normal myometrium, leading to hypertrophy of the uterine arteries (Figure 1). The actual fibroids are fed via a dense vascular network referred to as the perifibroid plexus, which is larger in diameter and has less tapering than the vessels supplying the surrounding myometrium.[16-18] The vessel diameter in the perifibroid plexus usually ranges from 500 to 1,000 µm. The size of embolic particles used should be targeted to the perifibroid plexus, not the smaller normal arterioles of the myometrium; smaller particles should be avoided because they lead to myometrial infarction. A variety of embolics are available for UFE, and many are FDA approved for the treatment of uterine fibroids (Table 1). This article reviews the literature on the currently available embolic agents to help guide the interventionalist.

Nonspherical Polyvinyl Alcohol

The first studies performed for UFE used nonspherical polyvinyl alcohol (nPVA).[7,19] True to its name, nPVA is irregular in shape and size. Given these characteristics, the particles tend to clump. Over minutes, these clumps break down and penetrate deeper into the smaller vessels, causing more distal embolization while allowing recanalization of the parent artery. Because of these unique properties, incomplete embolization may occur if the interventionalist is not familiar with proper nPVA embolization technique. By performing angiography several minutes after reaching the anticipated endpoint of embolization, one might see recanalization of the parent vessel, indicating further embolization may be required. Additionally, the irregular shape of the particles does not cause complete occlusion of the artery but instead creates a scaffold for thrombus and platelet aggregation, leading to occlusion in a manner analogous to a foreign body reaction.[20,21] Given these attributes, nPVA acts similar to the next size up of spherical particles; for example, 355–500-µm nPVA functions similarly to 500–700-µm spherical particles. Although there is no consensus regarding the appropriate size of nPVA for UFE, 355–500 µm is generally recommended. nPVA tends to remain in solution better when slurried with lower osmolality contrast. This can help decrease rates of parent catheter occlusion. If using a microcatheter, embolization with a larger French (eg, 2.8 F) is recommended to decrease risk of microcatheter occlusion, as this is one of the known disadvantages of nPVA compared with spherical particles.

Trisacryl Gelatin Microspheres

Trisacryl gelatin microspheres (TAGMs; Embosphere, Merit Medical Systems, Inc.) were FDA approved for UFE in May 2000.[22] These are tightly calibrated synthetic

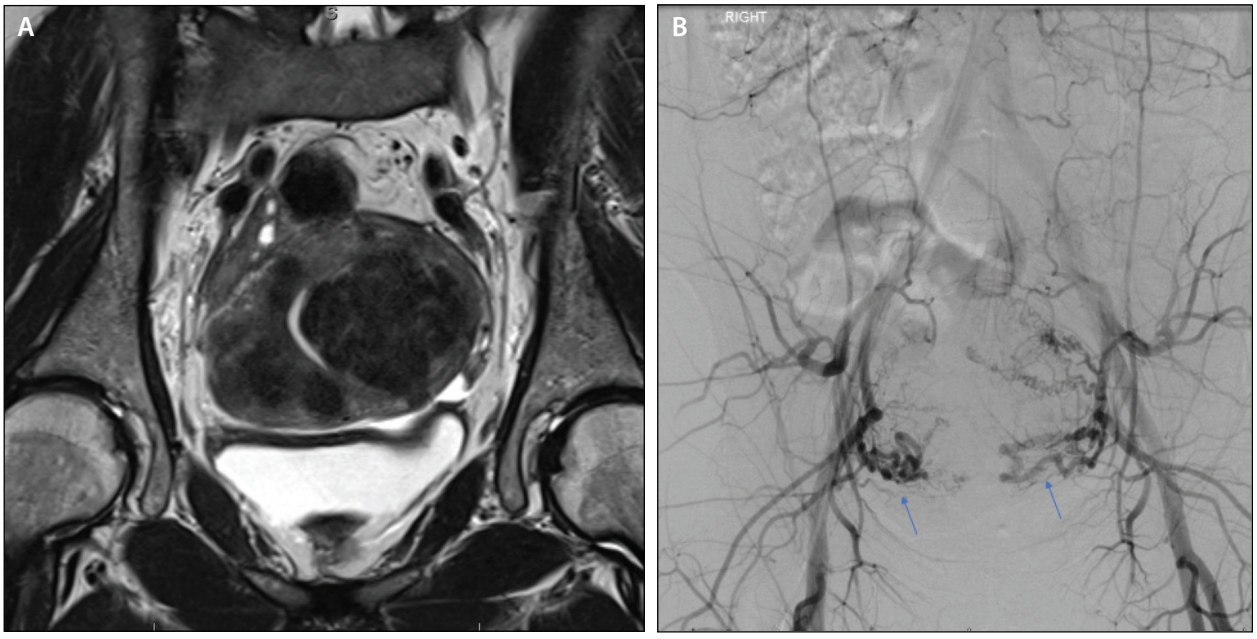

Figure 1. Coronal T2-weighted pelvic MRI (A) showing multiple intramural uterine fibroids and subsequent pelvic angiogram (B) in a 40-year-old woman with history of menorrhagia and bulk symptoms. The angiogram demonstrates bilateral uterine artery hypertrophy (arrows) with a hypervascular uterus.

microspheres that are hydrophilic and therefore do not aggregate, allowing for a "deeper" or more distal embolization. The mechanism of action is occlusion of the vessel lumen, not the inflammatory reaction seen with nPVA. The embolic must be carefully sized according to the targeted vessel lumen, the 500–1,000-µm perifibroid plexus.[20] For UFE, this is usually 500–700 µm, occasionally increasing to 700–900 µm. A randomized controlled study by Spies at al comparing TAGM and nPVA showed that a significantly higher volume of embolic was needed with TAGM, but there was no significant difference in pain severity postprocedure, fibroid infarction, patient satisfaction, or QOL.[22]

Spherical PVA

PVA also comes in a spherical form (sPVA). This was thought to be more comparable to calibrated microspheres such as TAGMs. In an animal study looking at a histologic analysis of arteries of six sheep uteri after embolization with 500–700 µm TAGM or sPVA microspheres, there was a histologic difference in the properties of the different microspheres.[23] TAGM was found to completely occlude the vessel while remaining spherical and homogeneous in structure. The PVA microspheres were found to be heterogeneous and conformed more to the shape of the vessels. Additionally, sPVA embolized more distally when compared with the same size TAGM.[23]

Several studies have looked at the outcomes of sPVA specifically for embolization of uterine arteries and have shown poorer performance when compared with other embolics. A single-institution retrospective analysis comparing conventional nPVA (400–600 and 300–500 µm) with sPVA (500–700 µm) found significantly less volume reduction of the fibroids with sPVA; additionally, sPVA was less efficacious in decreasing clinical symptoms.[24] sPVA also underperformed when compared with TAGM. Two separate prospective randomized studies comparing 500–700-µm sPVA and 500–700-µm TAGM showed poor clinical response and unacceptably low fibroid infarction rate.[25,26] This prompted a more recent randomized single-institution study comparing 500–700-µm TAGM to larger-sized sPVA (700–900 and/or 900–1,200 µm), which found no significant difference in QOL outcomes or fibroid shrinkage.[27] In summary, nPVA acts larger than the expected microsphere size due to the irregularity of the particle shapes, therefore it is recommended to embolize with a smaller size (300–500 vs 500–700 µm). sPVA functions as a smaller embolic than other microspheres of a similar size; therefore, embolization must be performed with larger microspheres (700–900 or 900–1,200 µm).

Bead Block

Bead Block (Boston Scientific Corporation) is a calibrated microsphere consisting of biocompatible hydrogel acrylamido PVA. Although it is FDA approved for UFE, multiple studies have shown higher rates of incomplete embolization on follow-up MRI.[28-30] One prospective study used larger

TABLE 1. CURRENTLY AVAILABLE EMBOLIC AGENTS FOR UFE

Company Name	Product Name	Composition	Shape	Sizes (μm)	FDA Approval for Uterine Fibroids?	CE Mark Approval for Uterine Fibroids?
Boston Scientific Corporation	Bead Block	Biocompatible PVA hydrogel	Spherical	100–300; 300–500; 500–700; 700–900; 900–1,200	Yes	Yes
	Contour embolization particles	PVA	Irregularly shaped flakes	45–150; 150–250; 250–355; 355–500; 500–710; 710–1,000; 1,000–1,180	Yes	Yes
Merit Medical Systems, Inc.	Bearing nsPVA embolization particles	PVA	Irregularly shaped particles	45–150; 150–250; 250–355; 355–500; 500–710; 710–1,000; 1,000–1,180	Yes	Yes
	Embosphere	Trisacryl with gelatin	Spherical	50–100; 40–120; 100–300; 300–500; 500–700; 700–900; 900–1,200	Yes	Yes
Terumo Interventional Systems	HydroPearl microspheres	Polyethylene glycol	Spherical	75 ± 30; 200 ± 75; 400 ± 75; 600 ± 75; 800 ± 75; 1,100 ± 75	Yes	Yes
Varian Medical Systems	Embozene microspheres	Hydrogel microspheres with Polyzene-F coating	Spherical, precisely calibrated	40; 75; 100; 250; 400; 500; 700; 900; 1,100; 1,300	Yes	Yes

Abbreviations: PVA, polyvinyl alcohol; UFE, uterine fibroid embolization.

particles (700–900 μm) and showed equivocal results to 500–700-μm TAGM.[31] Given these concerns, larger-sized (700–900 μm) Bead Block is recommended for UFE.

Embozene

Embozene (Varian Medical Systems) was introduced to the United States market in 2005 and received FDA approval for UFE in 2014. Embozene is a biocompatible nonresorbable hydrogel (sodium polymethacrylate) coated with Polyzene-F polymer. It differs from other microspheres in the sizes available and the tight calibration of the microspheres (Table 1).[32] Animal studies have shown that the microspheres have high predictability as to their distribution and a low level of inflammatory reactions.[33] Smeets et al published their experience using Embozene for UFE, demonstrating comparable outcomes to TAGM and gelfoam. However, it should be noted that the protocol changed during the study to larger-sized particles given the narrow range of microsphere sizes, due to cases of incomplete infarction with the smaller-sized particles. Therefore, no conclusions could be drawn regarding appropriate particle size, but the authors stated that the uniform size may actually serve as a disadvantage for UFE because of varied sizes of perifibroid plexus arteries.[34] An additional study found Embozene to be safe and efficacious, with acceptable patient QOL and tumor devascularization after UFE. It is important to note that particle size increased from 500 μm to 700 or 900 μm if an ovarian collateral was noted, with no cases of premature menopause reported.[35]

HydroPearl Microspheres

HydroPearl (Terumo Interventional Systems) is a tightly calibrated polyethylene glycol microsphere. Based on similarities with other FDA-approved embolic agents, it was approved for UFE by the FDA in 2015. To date, there have not been any published studies on the specific outcomes of UFE using HydroPearl or comparisons with other particles.

Gelfoam

Gelfoam is a biodegradable gelatin sponge used extensively in interventional radiology as a hemostatic agent, but it is not FDA approved for intravascular use. The first use of gelfoam in uterine artery embolization was described in 1979 in the setting of postpartum hemorrhage.[36] Gelfoam is considered a temporary hemostatic

agent, with recanalization of the vessel after weeks to months. Histologically, gelfoam causes necrotizing arteritis, leading to localized edema and foreign body reaction and subsequently inducing thrombosis.[1] Gelfoam is available in a powder or sheets from multiple different manufacturers. More recently, gelfoam is also available in precut cubes from Merit Medical Systems, Inc. (EmboCube). Gelfoam slurries are made by mixing a cut sheet of gelfoam with saline and contrast through a three-way stopcock. These small particles are not uniform in size, although they reportedly range from approximately 500 to 1,000 µm. This has been shown to cause more proximal embolization than other particles.[20] The appeal of gelfoam is the temporary nature of the embolic and the economic advantage compared to other particulates.

The majority of the literature supporting gelfoam use for UFE is from Japan, as the many other embolic particles were not commercially available early on. Studies of gelfoam in UFE show mixed results. In 2006, a group in Japan reported symptom control of 96% at 1 year and 89.5% at 5 years in 96 women who underwent UFE with gelfoam.[37] This same group has published extensively on outcomes using precut porous gelatin sponges available in Japan (Gelpart) showing equivocal imaging results and QOL compared with other microspheres[38,39]; interestingly, they found significantly more pain immediately after embolization when compared with TAGM.[40]

Several small single-center studies have been published comparing the outcomes of gelfoam to other embolic agents. A small (n = 20), double-blinded comparison of TAGM versus gelfoam embolization for uterine fibroids found significantly greater reduction in postembolization uterine volume in the TAGM group.[41] An additional small (n = 17), single-center, prospective study comparing patients embolized with gelfoam alone or used in conjunction with Embospheres found no significant difference in outcomes at 12 months.[42] There is no conclusion from the available data as to the efficacy of gelfoam compared with other agents for UFE.

AGENTS IN THE PIPELINE

Although there are no data to support the need for degradable products for UFE, patients are often concerned about the idea of a permanent embolic.

Two new temporary agents are on the horizon. Ekobi microspheres (IMBiotechnologies Ltd.), a poly(lactic-co-glycolic acid), degrade into carbon dioxide and water over 4 to 6 months. One unique benefit is that the particles appear echogenic on ultrasound. These are available in the United States and Canada in sizes ranging from 40 to 800 µm. A study in Canada is currently underway examining the outcomes in UFE.

Gel-Bead (Teleflex) is derived from porcine skin and degrades in 4 to 12 weeks. Gel-Bead is available in the United States in sizes ranging from 100 to 1,000 µm. A single-center study performed in the United Kingdom, which has been presented but not yet published, demonstrated equivocal outcomes with other embolic agents.

TIPS AND TRICKS FOR UFE

Just as there is no seamless embolic for UFE, there is no one right way to perform the procedure. The differences in how UFE is done can be seen from the beginning to the end. Described methods of arterial access include unilateral femoral, bilateral femoral, and radial. Operators debate whether closure devices or manual pressure should be done at the conclusion of the case.

Procedural Approach

Pelvic angiography should be performed from approximately the level of the renal arteries. This will ensure opacification of the pelvic vessels, providing a road map of the uterine arteries, and will also show if there is a hypertrophied ovarian artery supplying a fibroid. If a hypertrophied ovarian artery is visualized, we perform UFE in the standard fashion; however, we will be prepared to bring the patient back for a repeat procedure to embolize the ovarian artery if the patient has not sufficiently improved clinically. A study performed by Hu et al showed that ovarian artery embolization did not increase the rate of menopause onset or severity of symptoms when compared with standard UFE.[43] If needed, one should not be hesitant to embolize the ovarian arteries.

After selecting the uterine artery with the base catheter of choice (Roberts uterine catheter, Cobra, etc), we further select the uterine artery with a microcatheter (high flow or 2.8 F is recommended for embolization). This has several benefits. First, it helps decrease uterine artery spasm, something that is known to occur and can cause incomplete embolization. Second, if the endpoint is achieved when the microcatheter still contains embolic, it can be withdrawn and flushed on the back table, leaving the parent catheter within the uterine artery for completion angiography and administration of intra-arterial lidocaine. The microcatheter should be advanced past any cervicovaginal branches in the horizontal segment of the uterine artery prior to embolization. To help prevent vasospasm, we intra-arterially administer 200 µg of nitroglycerin to the uterine artery through the microcatheter before embolization. Embolization is subsequently performed using the embolic of choice, with care to decrease radiation to the patient via collimation, soft cones, and decreasing the fluoroscopy pulse rate to 3 frames/sec until nearing the end of embolization. Regardless of embolic used, embolization should be performed until near stasis in the main parent uterine artery, defined as stasis for five cardiac cycles. As discussed previously, if using nPVA, completion angiogra-

phy should be performed approximately 5 minutes after completion of embolization.

Pain Management

Pain management is a critical issue after UFE. While there are many ways to manage pain, the important focus is to have a plan that works for the interventionalists and the patient. Many places that perform outpatient UFE strongly advocate the used of hypogastric nerve blocks. In addition to moderate sedation (fentanyl and midazolam), we administer 30 mg of ketorolac while the patient is on the table immediately prior to embolization. Recent studies have shown that administration of intra-arterial lidocaine after embolization decreases patient pain and opiate use. The use of intra-arterial lidocaine before embolization leads to significant vessel spasm and high rates of incomplete embolization.[44] We have adopted this technique, administering 10 mL of 1% preservative-free lidocaine over 15 seconds through the base catheter into the uterine artery after embolization. Our experience mirrors that of the study by Noel-Lamy et al, which showed a reduction in postprocedural pain.[45] Our patients are admitted for overnight observation with a patient-controlled analgesia pump, with 30 mg of ketorolac and 25 mg of intravenous diphenhydramine scheduled every 6 hours. The next morning, the patient is transitioned to oral pain medication and discharged to home. Periprocedural antibiotics are given (cefazolin). The patient is not discharged to home with prophylactic antibiotics unless an intrauterine device is present.

CONCLUSION

Many embolic agents are available for UFE, both permanent and temporary. Based on the current literature, there is no one preferred embolic agent or correct size to use. When performing UFE, it is important to be comfortable with the nuances, mechanism of action, and sizing of your chosen embolic and procedure. ■

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