Patient Care and Uterine Artery Embolization for Leiomyomata

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J Vasc Interv Radiol 2004; 15:115–120

Abbreviation: UAE = uterine artery embolization

THROUGHOUT this document, the procedure under discussion will be referred to as uterine artery embolization for symptomatic leiomyomata or by the acronym UAE. Although the phrase "uterine fibroid embolization" (UFE) is used in other publications, for the purposes of clarity and scientific accuracy, the colloquial term "fibroid" will not be used in this document.

UAE is a percutaneous image-guided therapy that offers an alternative to chronic hormonal therapy and traditional surgical procedures, such as myomectomy and hysterectomy, to women with symptomatic leiomyomata (fibroids). The published experience indicates that this is an effective and safe therapy for leiomyomata.

UAE is unique among interventional radiology procedures in several ways. These differences require that the interventional radiologist performing UAE assume a far more active role in patient management than has traditionally been the case. With this position comes a great deal of responsibility that cannot be overemphasized. The Society of Interventional Radiology Task Force on Uterine Artery Embolization has developed this consensus statement to clarify the operating physician's responsibility to the patient and to address technical and procedural factors that will enhance the likelihood of a clinically successful treatment.

PATIENT SELECTION

At this time, the Task Force recommends that embolization be offered to only patients with symptomatic uterine leiomyomata. Because the symptoms associated with leiomyomata can also be caused by other processes, it is critical that patients undergo preprocedural evaluation that is adequate to confirm that their symptoms are in fact caused by leiomyomata or significantly contributed to by leiomyomata. It is equally critical that unrelated but potentially more important processes (such as ovarian malignancy) be excluded. The symptoms most commonly caused by leiomyomata include:

- Heavy menstrual bleeding;
- Pain (including pelvic, back, leg, and flank pain); and
- Bulk-related symptoms, including:
  - Pelvic pressure, heaviness or discomfort;
  - Abdominal bloating;
  - Urinary frequency or incontinence;
  - Ureteral compression; and
  - Rectal pressure.

Leiomyomata have also been implicated in infertility, subfertility, and complications during pregnancy, but it is not known what effect uterine embolization will have on these issues. Therefore, at this time, UAE is not recommended as a primary therapy for infertility in patients with leiomyoma who are reasonable candidates for and will accept myomectomy. For patients who desire children in the future, the decision to perform UAE should be made in the context of the patient's extent of disease and response to previous treatments and the potential for other treatments to control the symptoms without impairing ability to achieve and maintain pregnancy.

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DOI: 10.1097/01.RVI.0000109408.52762.35

The utility of UAE in treating women with leiomyomata and coexisting adenomyosis, or with adenomyosis alone, has not been established.

Whatever the indication for treatment, the most appropriate course of therapy for a given patient should be determined by the patient herself after consultation with a gynecologic care provider and an interventional radiologist, each of whom is knowledgeable about medical, surgical, and percutaneous treatment options.

CONTRAINDICATIONS TO UAE

A viable pregnancy would be an absolute contraindication to UAE. Active (untreated) infection is also a contraindication for embolization of an organ because of the likelihood of abscess formation and related septic complications. UAE for leiomyomata would also be contraindicated when leiomyosarcoma or other gynecologic malignancy is suspected unless the procedure is being performed strictly for palliation or as an adjunct before surgery.

Relative contraindications to any endovascular intervention would include coagulopathy, severe contrast material allergy, and renal impairment, all of which can often be ameliorated. Relative contraindications to pelvic embolization include immunocompromise, previous pelvic irradiation or surgery, and chronic endometritis or a partially treated pelvic infection. All these conditions may interfere with the normal healing response, alter the normal barriers to infection, and place the woman at a higher risk of complication.

Relative contraindications to UAE specifically include the desire to maintain childbearing potential, as preservation of fertility cannot be assured based on the current literature. However, uncomplicated pregnancies and normal deliveries have been reported after UAE, so this procedure may still be the preferred option for women who are not candidates for or who refuse myomectomy.

Other relative contraindications specific to UAE might include the concurrent use of a gonadotropin-releasing hormone agonist, as this medical treatment for leiomyomata may impact on the technical success of the procedure. Extensive endometriosis or adenomyosis may be responsible for menorrhagia or dysmenorrhea symptoms, often coexisting with leiomyomata, and UAE may not be beneficial to either situation. Finally, a subserosal leiomyoma that is sufficiently pedunculated (attachment point $< 50\%$ of the diameter) can be at risk for detachment from the uterus, a situation that necessitates surgical intervention.

PREPROCEDURAL EVALUATION

Medical History

Each patient should have a complete gynecologic and general medical history recorded, including symptoms, pregnancy history, history of pelvic infection, most recent Papanicolaou test or other pathologic results, allergies, current medications, and other medical conditions.

General Physical Examination

Before treatment, all patients should have a general physical examination of sufficient detail to exclude other significant illnesses. This examination should include a focused vascular examination.

Gynecologic Examination

Every patient who undergoes uterine embolization should have a complete gynecologic examination by a physician (or other qualified health professional) with training and experience in gynecologic care. This examination should confirm the diagnosis of leiomyomata, verify that the symptoms being experienced by the patient are related to the leiomyomata, and exclude other significant pathology. This examination should be performed within 12 months before the procedure.

PREPROCEDURAL TESTING

Laboratory Testing

Given the minimal expense associated with simple laboratory tests and the variability of menstrual histories, a complete blood count should be obtained for each patient. At a minimum, a recent complete blood count should be available for patients with heavy menstrual bleeding.

For patients with a history suggesting an underlying bleeding disorder that may be contributing to menstrual bleeding or may complicate percutaneous therapy, activated partial thromboplastin time and prothrombin time with international normalized ratio may be measured along with complete blood count. If there is a history suggesting possible renal insufficiency, blood urea nitrogen and/or serum creatinine levels should be measured.

Evaluation of a patient's reproductive hormone status is not routinely performed, even though some authors have advocated measuring serum follicle-stimulating hormone levels to determine menopausal status. Because of the variability in serum follicle-stimulating hormone levels throughout a patient's menstrual cycle and the pulsatile nature of its secretion, measurement of the serum follicle-stimulating hormone level is of uncertain benefit. No general consensus has been reached as to the role of routine hormone assay in patients who will undergo UAE.

Imaging

Cross-sectional imaging of the pelvis—preferably ultrasonography or magnetic resonance (MR) imaging—should be performed before embolization. This study is intended to confirm the diagnosis of leiomyomata and to exclude other pelvic pathology. MR imaging examinations may provide a more accurate assessment of leiomyoma location, size, and impact on adjacent structures and are more accurate in the diagnosis of adenomyosis. The use of MR imaging is also indicated when previously performed imaging studies have incompletely visualized the pelvic contents or when, in the judgement of the examining physician, this modality will provide information important to him or her in deciding whether to offer embolization therapy.

Papanicolaou Test

The patient should have a normal Papanicolaou test result within 12 months before UAE. Patients with ab-

normal Papanicolaou test results should be referred to their gynecologic care provider for follow-up evaluation and treatment.

Endometrial Sampling

Patients who have continuous bleeding, very prolonged menstrual periods, significant intermenstrual bleeding, or bleeding after menopause may be at increased risk for endometrial hyperplasia or endometrial malignancy. The patient's gynecologic care provider should be consulted to determine whether an endometrial biopsy (or dilation and curettage) should be performed before UAE in this group of patients.

PREPROCEDURAL CARE

Outpatient Consultation

Each patient should be seen and evaluated in an outpatient setting to determine whether embolization is indicated and whether it is the best option for the patient. This consultation should be held on a day other than that of the procedure itself. In urgent or emergent cases, a same-day consultation (inpatient or outpatient) may be necessary.

A physician from the UAE service should meet with the patient during the inpatient or outpatient consultation to obtain and/or review pertinent findings of the patient's history, physical examination, and imaging studies and to provide the patient with an appropriate recommendation regarding treatment. This discussion should include the likely suitability of the patient for other treatment options. The participation of nurse practitioners, physician assistants, or nurses in obtaining baseline history, physical findings, and related information is acceptable, as is their educating patients about the procedure, periprocedural care, and follow-up. However, these physician extenders should not provide the definitive opinion as to the appropriateness of UAE versus other treatment options in a given patient. Rather, that responsibility must be given to physician providing the consultation.

To ensure proper continuity of care, the physician providing the consultation should also perform the procedure. When this is impractical, the treating physician should, at a minimum, meet the patient before the procedure in an area outside the procedure room and review with her the treatment plan.

PERIPROCEDURAL HOSPITAL CARE

The patient should be admitted by the interventional radiologist performing the procedure or, in cases in which interventional radiology admitting privileges are not available, by a gynecologist or other physician who is actively involved in the patient's care. During hospitalization, most patient-care issues will revolve around pain and nausea management. Because interventionalists are experienced with patient management after other embolotherapeutic procedures, they should assume the lead role in patient management during the hospitalization after UAE; postprocedural management of these patients should not be left to gynecologists and primary-care physicians who are less familiar with the treatment and its sequelae. In some centers, the initiation of pain management may require consultation with anesthesia services. This is acceptable after an appropriate care plan routine has been established.

Care during the Embolization Procedure

Intraoperative pain control.—Most centers use conscious sedation to assure patient comfort during the embolization procedure, although some operators prefer epidural or spinal analgesia. General anesthesia is neither required nor recommended. Each angiographic section that uses conscious sedation must adhere to the conscious sedation policy of its own institution. Because patients usually experience pelvic pain immediately after the procedure, the personnel charged with monitoring sedated patients should be prepared and equipped to manage sedation and the analgesia that will be required immediately after the procedure.

Periprocedural antibiotics.—Although infectious complications have been reported in the periprocedural interval, there have been no studies to date to determine whether antibiotic prophylaxis reduces that risk. In addition, although prophylactic antibiotics are commonly given, there is no consensus as to which agents should be used.

Although the Task Force cannot make any recommendations at this time, it is imperative that each patient be instructed as to the signs and symptoms of possible infection, and each patient's recovery should be followed carefully to allow early detection and treatment of infection.

Monitoring of radiation exposure.—Because fluoroscopy and angiographic filming are used during UAE, the patient will be exposed to ionizing radiation. All procedures and radiation exposure should be governed by the principle of "As Low As Reasonably Achievable (ALARA)." The fluoroscopy time and number of angiographic exposures should be recorded and the levels monitored as part of the section's ongoing quality-improvement program. In addition, many angiographic machines provide detailed information regarding the patient's radiation dose (such as dose–area product or peak skin dose); when such information is available, it should also be recorded and tracked.

POSTPROCEDURAL CARE

Pain Management

Uterine embolization for leiomyomata usually causes pain for several hours, and, on occasion, the pain may be severe. It is incumbent on the treating physician to provide an appropriate pain-management strategy for all patients. Interventional radiology physicians who are trained and experienced in post-UAE pain management and who are licensed to use narcotic analgesics should administer this care themselves. Other interventional radiology physicians, until they have achieved the level of expertise necessary to manage pain independently, may instead identify another physician qualified to assume this responsibility. The transfer of pain-management responsibility must not result in a delay in the institution of analgesia and must therefore be coordinated in advance. Therefore, each section must

develop with appropriate consultants a plan for pain management before treatment of any patients. In particular, consultation with anesthesiologists or pain-management specialists may be invaluable in developing the best patient-care plan. This plan should be written, and a set of standard orders should be developed based on it. Nursing staff in the interventional area and hospital units caring for these patients must be in-serviced on the plan so they will understand the nature of the procedure and the care that should be provided.

At this time, there is no consensus regarding the best method of pain management. Patient-controlled analgesia with use of intravenous morphine, meperidine, hydrocodone, or fentanyl has been used effectively in most centers. Others use epidural analgesia, with either a single dose of long-acting narcotic or a continuous infusion of analgesia, whereas still others prefer spinal analgesia. Finally, some operators have used and advocated all-oral medication regimens. Whatever the method used, each group offering the UAE procedure must be prepared with an approach that can be instituted immediately after the procedure and monitored for adequacy while the patient is hospitalized.

Nausea Control

Nausea is a common side effect of the embolization procedure and/or the medications used for pain control. Some practices have advocated prophylactic use of antiemetic agents, whereas others use an "as-needed" approach. Whichever approach is chosen by a given practice, some mechanism for addressing nausea should be incorporated into the plan of pain management.

Assessing the Need for Hospital Admission

In many interventional practices, UAE is followed by overnight observation in a hospital setting. The purpose of this admission is to assure adequate pain control. However, many practices have been successful in discharging patients the day of the procedure. The decision regarding discharge must be made on a case-by-case basis, and should be based on the patient's level of comfort rather than the potential difficulty of making an admission. For interventional radiology practices that are not physically connected to a hospital, a mechanism for transferring to a hospital those patients needing admission should be in place before patients are treated. Interventional radiologists who do not have admitting privileges should have in place a mechanism for having patients admitted by another physician who is familiar with the patient. All patients should successfully complete a trial of pain control with oral agents before leaving the hospital.

In-Hospital Care

A member of the interventional team must be available by telephone or pager during the patient's entire hospitalization. This is true regardless of the service to which the patient has been admitted. The patient should be evaluated by the operating physician within several hours of completing the procedure to assess pain control and any complications. The patient must also be evaluated by the operating physician before discharge and be given instructions for home care and follow-up. Written discharge instructions should be provided for the patient. Although nurse practitioners or physician assistants may assist with in-hospital care, the operating physician should take a leading role in this process and, in particular, discuss with the patient (and family members when appropriate) the outcome of the procedure and anticipated postprocedural course.

Care after Discharge

Oral antiinflammatory agents and narcotics are commonly used for several days after the procedure. Each group performing UAE should have a postprocedural management strategy developed to provide for pain and nausea after discharge.

As part of the management plan, each patient should be contacted 24–48 hours after discharge to determine the adequacy of pain and nausea control and to screen for any potential early complications.

The patient must have a telephone number for 24-hour contact with a member of the physician team caring for the patient. An interventional radiologist must be available for patient consultation during the postprocedural recovery. The interventional team should be the point of first contact for problems the patient may encounter.

If possible, the patient should return for a postprocedural outpatient visit 1–3 weeks after the procedure. At this visit, healing of the puncture sites may be confirmed, screening for unusual symptoms or potential problems can be done, and the patient may be reinstructed on subsequent follow-up plans.

Follow-up imaging is indicated 3–6 months after the procedure. This is useful in determining whether all existing leiomyomata have been infarcted and begun to decrease in volume and will also help determine whether any uterine or adnexal complications have occurred. In addition, postprocedural imaging provides a "new baseline" measurement of leiomyoma volume against which any subsequent increase in size (which might indicate leiomyosarcoma) can be compared.

Physicians performing UAE must be prepared to provide long-term follow-up for their patients. This is important for monitoring the control of symptoms, but also for detecting complications that may occur. Late infections, expulsion of portions of leiomyomata, chronic endometritis, chronic vaginal discharge, and cessation or irregularity of menses have all been described after UAE and may develop more than a year after the procedure.

ANGIOGRAPHIC EQUIPMENT

To ensure the best possible success and safety with this procedure, high-quality angiographic equipment should be used. In general, this implies an angiographic unit in a fixed installation, rather than portable C-arm equipment. The equipment must have adjustable collimators. The machine must be capable of serial radiography and digital subtraction. Ideally, the following features would also be present on the angiographic equipment:

- Reduced-dose pulsed or low-dose continuous fluoroscopy and

last image hold, both of which are important in reducing radiation exposure;
- Digital arteriographic imaging with a 1,024 matrix size;
- Digital roadmapping;
- Imaging chain suspended from a C-arm, U-arm, or a combination to allow oblique and compound angulation of the fluoroscope;
- Automatic cumulative fluoroscopic timer;
- Mechanism for recording patient radiation dose, such as dose–area product or cumulative dose at the interventional reference point or skin entrance dose. Some interventional rooms may report radiation dose as the percent of erythema dose (2 Gy).

ANGIOGRAPHIC TECHNIQUE

Radiation exposure to the patient is directly impacted by technical factors under the operator's control. Although each individual case is unique and may require specific imaging configurations for success, there are several variables that increase patient dose, and they should be used only as necessary to assure technical success:
- Multiple and prolonged image acquisition;
- Image magnification;
- Oblique angulation of the imaging chain;
- Large fields of view (inadequate collimation);
- Large air gap between the patient and the image intensifier;
- Roadmap imaging in some imaging chains (which may without notification disable pulsed or low-dose fluoroscopy; this issue should be discussed with the equipment vendor).

UAE TECHNIQUE

Timing

There are no currently available data to indicate an ideal time for UAE relative to the menstrual cycle. For patients using gonadotropin-releasing hormone agonists and whose therapy with these agents cannot be discontinued as a result of their severity of bleeding, UAE should be performed immediately before a scheduled injection (that is, at the nadir of circulating drug levels).

Access Site

Most operators use a single femoral access site for UAE, whereas others have advocated bilateral access. Some interventional radiologists may alternatively use an axillary, brachial, or radial approach. There are no data to indicate that any of these routes is safer or more efficacious than any other. The choice of an access site (or sites) should be made by the operator based on his or her personal preference and the vascular anatomy of the patient

Target Arteries

Successful treatment of uterine leiomyomata requires distal occlusion of all branches feeding the uterine leiomyomata. Therefore, both uterine arteries should be catheterized and treated unless there are congenital or postoperative variants that prevent bilateral treatment.

Large uterine leiomyomata may attract collateral blood supply from the ovarian arteries or through adhesions from adjacent pelvic structures. The likelihood of clinical success after UAE will be reduced if these collateral vessels are not recognized and treated. In many cases, but not all, embolic occlusion of the collateral supply can be accomplished without significant risk to adjacent structures.

There is no current consensus regarding the appropriateness and timing of searching for and treating collateral blood supply. Some operators obtain an initial aortogram with the catheter at the level of the renal arteries and image centering over the pelvis, anticipating that this will identify collateral vessels. Others have suggested that this study would be more appropriately performed at the end of embolization or, alternatively, at a later date only if the degree of clinical improvement is less than anticipated.

Because embolization of the ovarian artery may significantly impair ovarian function, the potential need for, and consequences of, this approach should be specifically discussed with and approved by the patient during preprocedural consultations.

Agents

The desired level of arterial occlusion in UAE is quite distal: at the perforating branches. Proximal occlusion of larger arteries with coils or similar agents would not be expected to provide clinical success. At present, distal embolization can best be accomplished with particulate agents. Those in current use include polyvinyl alcohol, tris-acryl gelatin microspheres, and gelatin sponge particles. The latter agent is not approved by the Food and Drug Administration for intraarterial use, but is commonly employed in this off-label capacity. Polyvinyl alcohol and gelatin microspheres are approved by the Food and Drug Administration for intraarterial use, but the indication for polyvinyl alcohol is for neurovascular lesions. Gelatin microspheres have a specific indication for use in UAE. Despite these differences in approval status, all three agents appear to be equally safe and effective.

Endpoint

There is general consensus that UAE performed with polyvinyl alcohol or gelatin sponge particles should be continued until there is complete occlusion of flow in the main uterine artery. Similarly, there is general consensus that UAE performed with gelatin microspheres can be terminated when the branch arteries penetrating the leiomyoma have been occluded, even if significant antegrade flow is still present in the main uterine artery and its first branches. However, it should be noted that these suggested endpoints are based on clinical observation rather than objective evidence.

Repeat Treatment

Inadequate clinical improvement or volume reduction on follow-up imaging may lead to a second arteriographic examination and repeat embolization. This may be appropriate if, on imaging studies, there is evidence of continued perfusion of the leiomyomata. Alternatively, if all the visualized lesions demonstrate fibrotic change and an absence of perfusion, repeat treatment is unlikely to be of

use. MR imaging is of particular utility in making this determination.

If repeat treatment is performed, it should be preceded by a discussion with the patient that specifically addresses the risks of ovarian injury. This discussion is important because ovarian collateral supply is a common cause for treatment failure, and more-aggressive embolization during a second treatment may result in ovarian injury and cause accelerated ovarian failure.

Acknowledgments: Dr. James Spies authored the first draft of this document. Dr. R. Torrance Andrews served as topic leader during the subsequent revisions of the draft. Dr. David Sacks is the SIR Standards Division Councilor.