

Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomata

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Abbreviation: UAE = uterine artery embolization

PREAMBLE

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Europe (CIRSE) and the Society of Interventional Radiology (SIR) is comprised of experts in a broad spectrum of interventional procedures from the private and academic sectors of medicine. Generally, Standards of Practice Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such they represent a valid broad expert constituency of the subject matter under consideration for standards production.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

METHODOLOGY

The CIRSE and SIR Standards of Practice documents are produced using the following process. Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed with use of electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The

qualitative weight of these articles is assembled into an evidence table (Appendix 1), which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members with a Modified Delphi Consensus Method (1,2) (Appendix 2). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee members, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions are made to create the finished standards document. Before its publication the document is endorsed by the CIRSE Executive Committee and the SIR Executive Council.

UTERINE ARTERY EMBOLIZATION

Throughout this document, the procedure under discussion will be referred to as uterine artery embolization (UAE) for symptomatic leiomyomata. Although the phrase "uterine

fibroid embolization" is used in other publications, for the purposes of clarity and scientific accuracy in this document, the colloquial term "fibroid" will not be used.

Transcatheter embolization of the uterine arteries for the express purpose of devascularizing leiomyomata was first reported by Ravina et al in 1995 (3). The procedure was based on established techniques for treating pelvic bleeding related to trauma or gynecologic emergencies such as postpartum hemorrhage. Goodwin et al (4) reported the first experience in the United States of treating leiomyomata by UAE in 1997. By the year 2000, it was estimated that more than 10,000 UAE procedures had been performed worldwide, based on survey data obtained by SIR (5). This number continues to increase.

Such rapid adoption of UAE into the standard practice of interventional radiology has been possible because training in transcatheter embolization techniques is a required part of all fellowship programs in interventional radiology. This training includes the safe handling and delivery of commercially available embolic agents used for this purpose. Most UAE procedures are technically successful and require only conscious sedation and analgesia, with few complications.

A registry has been created for the accrual and analysis of outcomes data. The registry is cosponsored by SIR's Cardiovascular and Interventional Radiology Research and Education Foundation (CIRREF; now known as SIR foundation) and private industry and is administered by the Duke Clinical Research Institute, with input from the U.S. Food and Drug Administration. The aims of the registry are to address the issues of efficacy and safety, with specific focus on the impact of UAE on fertility and sexual function, and to develop strategies to minimize recurrences and reduce the risk of injury to the ovaries.

These guidelines are intended for use in quality-improvement programs that assess UAE to insure the standard of care expected of all physicians who perform this procedure. The processes to be monitored include (i) patient selection, (ii) performance of the procedure, and (iii) postprocedural follow-up. Assessment of outcome measures is also desirable, and these include

technical success, complications, efficacy, and recurrence rates, which are assigned threshold levels.

DEFINITIONS

The goal of UAE is to deliver particulate emboli, typically polyvinyl alcohol (PVA) particles, PVA microspheres, or gelatin-coated tris-acryl polymer microspheres, into both uterine arteries for the purpose of occluding or markedly reducing uterine blood flow at the arteriolar level, producing an irreversible ischemic injury to the leiomyomata while avoiding permanent damage to the uterus. Percutaneous arterial access may be achieved through one or both femoral arteries, depending on operator preference and constraints of the native anatomy. Selective catheterization of the uterine arteries may require the use of microcatheters and/or vasodilator agents to reduce the likelihood of technical failure resulting from arterial spasm or dissection. After the procedure, hemostasis can be achieved by manual compression or a vascular closure device. Administration of intravenous narcotics for pain control and the use of antiinflammatory and antiemetic medications are standard. UAE usually requires an overnight hospital stay for observation, although for selected patients, an immediate oral regimen and same-day discharge may be appropriate (6).

Technical success is defined as occlusion or marked reduction in blood flow in both uterine arteries. Successful embolization of only one uterine artery is still considered a technical failure unless only a single uterine artery is present, as the intention is to reduce blood flow bilaterally. Arterial spasm may prevent successful cannulation or result in premature reduction of blood flow, but the latter situation may be recognized as a true technical failure only retrospectively after infarction of the fibroids has failed to occur (best confirmed by contrast-enhanced MR imaging).

Clinical success is defined as the resolution of presenting symptoms, such as menorrhagia or bulk-related pain, bloating, urinary frequency, or constipation, without additional therapy.

Nontarget embolization is defined as the unintended release of an embolic agent into a vascular territory outside

the targeted area. In the pelvis, the areas of concern are the ovaries, urinary bladder, intestine, muscles, and nerves, in which nontarget embolization can result in symptoms of pain and/or infarction and the possibility of temporary or permanent disability.

Postembolization syndrome is defined as the occurrence of pelvic pain, low-grade fever, nausea, vomiting, loss of appetite, and malaise in the first few days after undergoing UAE. This is an expected aspect of recovery, with a variable degree of intensity, and presumably results from the release of cytokines related to ischemia and/or degeneration. This process should not be considered a complication of UAE unless unplanned medical therapy or prolonged hospitalization is required.

Endometritis is defined as inflammation of the inner lining of the uterus (endometrium) after UAE, which manifests as pelvic pain, watery vaginal discharge, fever, and/or leukocytosis, and can occur days to weeks after the procedure. Etiologies include infectious and noninfectious causes.

Leiomyoma infection is defined as bacterial infection of one or more leiomyomata as a result of (i) colonization of devitalized fibroid tissue by blood-borne pathogens or (ii) the ascent of vaginal organisms, the latter occurring more commonly in the setting of arrested transcervical passage of a leiomyoma. Symptoms and signs include abdominal or pelvic pain, fever, and/or leukocytosis.

Uterine (myometrial) infection is defined as infection of the uterus, possibly as a result of necrosis of all or part of the uterus, which manifests as abdominal or pelvic pain, vaginal discharge, fever, and/or leukocytosis. Initial therapy includes intravenous antibiotics and medications to reduce pain and inflammation, but ultimately, surgical management may be necessary.

Transcervical leiomyoma expulsion is defined as detachment of leiomyoma tissue from the uterine wall and subsequent transvaginal passage, most commonly occurring with submucosal leiomyomata that have narrow points of attachment. This process may be associated with uterine contractions, abdominal pain, fever, nausea, vomiting, and vaginal bleeding or discharge. Surgical intervention may be necessary in the event of arrested pas-

sage, with all or some of the leiomyoma retained within the uterus or endocervical canal, causing persistent discomfort and predisposing to infection.

Premature ovarian failure is defined as the presence of amenorrhea, increased follicle-stimulating hormone levels, and clinical symptoms suggestive of menopause after undergoing UAE. Such symptoms include night sweats, mood swings, irritability, and/or vaginal dryness. This must be differentiated from transient amenorrhea, which lasts at most a few menstrual cycles and is not typically associated with increased follicle-stimulating hormone levels or menopausal symptoms.

Although practicing physicians should strive to achieve perfect outcomes (ie, 100% success, 0 complications), in practice, all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality-improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure, eg, major complications. Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates decrease below a (minimum) threshold or when complication rates exceed a (maximum) threshold, a review should be performed to determine causes and to implement changes if necessary. For example, if the incidence of persistent symptoms is one measure of the quality of UAE, values in excess of the defined threshold, in this case 15%, should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Therefore, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed to higher or lower values to meet its

own quality-improvement program needs.

Complications can be stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight; see Appendix 3). The complication rates and thresholds below refer to major complications.

INDICATIONS

Patient selection is a complex process that is influenced by presenting symptoms, physical examination, imaging findings, and patient preferences. Identification of appropriate candidates for UAE relies on criteria for which no definite guidelines may exist, such as leiomyoma size, or criteria that are subjective, such as the perceived severity of symptoms. Nevertheless, practical measures can be adopted for a given setting that allow for an appropriate standard of care, with the goal of ensuring proper patient selection, periprocedural management, and follow-up treatment.

The presence of uterine leiomyomata should be confirmed by technically adequate imaging—either ultrasonography (US) (7) or magnetic resonance (MR) imaging (8)—and the likelihood of the leiomyomata causing the main symptom(s) should be determined. US is readily available in most practices. MR has been shown to provide additional information that influences treatment planning in women with leiomyomata (9). Consultation before UAE in an outpatient setting provides the physician an opportunity to review the patient's history, physical examination, and imaging findings and gives patients time to consider all options before proceeding. Informed consent should be obtained by the physician(s) who will be performing the procedure; the discussion of potential complications should be tailored to the specific procedural technique used by that practitioner. In that context, risks and benefits should be discussed in detail.

Any and all treatment options

should be presented, with the understanding that, for patients interested in gynecologic alternatives, additional consultation will be required. Choice of embolic agent(s), route(s) of vascular access, and the anticipated use of an arterial closure device should be discussed, and descriptions of the process of admission to the hospital (and by whom), the immediate post-UAE recovery period, convalescence and medications at home, and the time expected away from work should also be made. Written materials given at the time of consultation can enhance this process. Contact information should be given to patients so they can access a responsible physician on a 24-hour availability basis if they perceive that a problem has arisen. Clinical follow-up is the responsibility of the radiologist(s) performing the procedure and should be arranged for the appropriate time interval(s) during which symptom improvement can reasonably be assessed, preferably in person, and further imaging can be obtained as the situation warrants.

Symptoms of uterine leiomyomata fall into two general categories: mass effect and abnormal uterine bleeding (dysmenorrhea, menorrhagia, and menometrorrhagia). Symptoms may vary depending on the size and location of the leiomyomata. Submucosal leiomyomata are usually responsible for abnormal uterine bleeding, although intramural leiomyomata can encroach on the endometrial cavity and produce menorrhagia. In contrast, it is usually large intramural and/or subserosal leiomyomata that result in mass effect on adjacent organs and corresponding symptoms, such as urinary frequency, urgency, and/or constipation.

There is not yet an established schedule of absolute or relative contraindications. A viable pregnancy would be an absolute contraindication to UAE. Active (untreated) infection is also a contraindication to embolization of any organ because of the likelihood of abscess formation and related septic complications. UAE for leiomyomata would also be contraindicated when leiomyosarcoma or adnexal malignancy is suspected unless the procedure is being performed for palliation or as an adjunct to surgery.

Relative contraindications to any endovascular intervention would in-

Table 1
Expected Outcomes

Category	Reported Rate (%)
Anticipated leiomyoma size reduction	50–60
Anticipated uterine size reduction	40–50
Anticipated reduction of bulk symptoms	88–92
Elimination of abnormal uterine bleeding	>90
Successful elimination of symptoms	85

Table 2
Complications in UAE

Complication	Reported Rate (%)	Suggested Threshold (%)
Transient amenorrhea	5–10	10
Permanent amenorrhea		
Age <45 years	0–3	3
Age >45 years	7–14	15
Transcervical fibroid expulsion	0–3	5
Non-infectious endometritis	1–2	2
Endometrial or uterine infection	1–2	2
Deep venous thrombosis or pulmonary embolus	<1	2
Uterine necrosis	<1	1
Nontarget embolization	<1	<1

clude 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 of these conditions may interfere with the normal healing response, alter the normal barriers to infection, and place the patient at a higher risk of complication.

Relative contraindications to UAE specifically include the desire to maintain childbearing potential because preservation of fertility cannot be assured based on the current literature. However, uncomplicated pregnancies and normal deliveries have been reported after UAE (10,11), so this procedure still may be the preferred option for women who are not candidates for 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 the technical success of the procedure. Extensive endometriosis or adenomyosis may be responsible for menorrhagia or dysmenorrhea symptoms, often coexisting with fibroids, 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.

INDICATIONS FOR UAE FOR SYMPTOMATIC LEIOMYOMATA

UAE is indicated for the presence of uterine leiomyomata that are causing significant lifestyle-altering symptoms, specifically mass effect on the bladder or intestines, and/or dysfunctional uterine bleeding that is prolonged, associated with severe dysmenorrhea, or is causing severe anemia. The recommended threshold is 100%. Related issues include fertility potential and feasibility of alternative medical or surgical therapies.

SUCCESS RATES

Technical

The recommended threshold for successful embolization of both uterine arteries is 96%.

Outcome

In most instances, reduction in uterine and leiomyoma volumes becomes noticeable several weeks after embolization and continues for 3–12 months afterward (Table 1).

Recurrence

The recurrence rate after UAE is unknown, although one series reported a symptomatic recurrence rate of 1.2% after 81 UAE procedures (12). At present, no preventive measures exist. Even with complete infarction of all leiomyomata, a viable uterus may give rise to new leiomyomata. The

time course to symptoms will depend on age and the onset of menopause. The threshold for recurrence of leiomyoma-related symptoms is unknown.

Complications

Although major complications can occur during or as a result of UAE, they are rare (13). Suspicion of infection has prompted hysterectomy on occasion (4), but it is important to note that, after UAE, there are no imaging findings that are reliable for the diagnosis of infection (14). Uterine necrosis is an extremely rare occurrence (15), especially if the normal pelvic collateral circulation is intact. Death may occur if a major complication goes unrecognized and is not addressed in a timely fashion. As of June 2003, there have been three reports of deaths that have occurred within 30 days of UAE, two from uterine infection and overwhelming sepsis (16,17) and one from massive pulmonary embolism (18).

It is often difficult to discern the point at which postembolization syndrome is severe or persistent enough to constitute a complication. Symptoms that require readmission to the hospital after discharge would be considered a complication, with classification into major versus minor depending on the length of hospitalization and need for additional interventions. Readmission for pain control during the first week after the procedure usually requires only a one-night observation stay and would be considered a minor complication. This has been reported to occur at rates of 0–9% (6).

Menstrual disturbances are not uncommon after UAE and are thought to be caused by undetected nontarget embolization of the ovaries via uterine-to-ovarian arterial interconnections (19). However, a direct effect of UAE on the uterus may also be responsible. Post-UAE amenorrhea is usually limited to a few cycles (20) and is not considered a major complication. Permanent amenorrhea may occasionally result, which appears to be age-related (21,22). This would be classified as a major complication (permanent adverse sequela), although some patients may not view it as such. There have been anecdotal reports of minor complications, such as petechial rash on the torso and limbs (1%–7%) (23). However, none of the major or minor complications described to date appear to be unique to any specific embolic agent.

Complications related to the angiographic components of this procedure are not addressed herein because they have already been elucidated in the SIR Standards for Diagnostic Angiography (24). However, it should be pointed out that embolization procedures can entail significant fluoroscopic doses, and dose-reduction efforts are imperative to avoid skin burns and, in the setting of UAE, the potential for ovarian injury (25). Generally, the incident doses for UAE are an order of magnitude less than those required to produce such effects (26).

Reported complication-specific rates in some cases reflect the aggregate of major and minor complication. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ® system national database. Published complication rates and suggested thresholds are listed in **Table 2**.

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Therefore, we recommend that complication-specific thresholds should usually be set higher than the complication-specific reported rates listed herein. It is also recognized that a single complication

can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, eg, early in a quality-improvement program. In this situation, the overall procedure threshold is more appropriate for use in a quality-improvement program.

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APPENDIX 1: EVIDENCE TABLE

(See following page)

APPENDIX 2: METHODOLOGY

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Consensus on statements in this document was obtained with a modified Delphi technique (1,2).

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this docu-

ment are available upon request from SIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

APPENDIX 3: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

- A. No therapy, no consequence, or
- B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

- C. Require therapy, minor hospitalization (<48 hours),
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours),
- E. Have permanent adverse sequelae, or
- F. Result in death.

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Appendix 1: Evidence Table

Study	No. of Pts.	Mean Duration of Follow-up (Months)	Improvement in Menorrhagia	Improvement in Pressure/Pain %	Mean Fibroid Volume Reduction (%)	Reported Complications
Hutchins et al, 1999 (25)	305	12	86* 85† 92‡	64* 77† 92‡	48	Hysterectomy (<i>n</i> = 1); puncture site hematoma (<i>n</i> = 4); readmission for pain (<i>n</i> = 2)
Goodwin et al, 1999 (26)	60	16.3	81	93	48.8	Hysterectomy for infection (<i>n</i> = 1)
Ravina et al, 1999 (27)	184	29	90	-	50-100 in 87% of patients†	Hysterectomy for uterine necrosis and bowel obstruction (<i>n</i> = 1); fibroid expulsion (<i>n</i> = 6)
Siskin et al, 2000 (4)	49	-	88.5	-	47.5†	Hysterectomy for prolonged pain (<i>n</i> = 1); prolonged fever resolved at 6 weeks (<i>n</i> = 1)
Pelage et al, 2000 (28)	80	-	94	-	20§ 52†	Hysterectomy for infection (<i>n</i> = 1); amenorrhea (<i>n</i> = 4); fibroid expulsion (<i>n</i> = 4)
Brunereau et al, 2000 (29)	58	12	90* 92† 93‡	-	23* 43† 51‡	No hysterectomy; external iliac artery dissection (<i>n</i> = 1)
McLucas et al, 2001 (30)	167	6	82†	-	49† 52‡	Hysterectomy for infection (<i>n</i> = 1); fibroid expulsion (<i>n</i> = 8)
Andersen et al, 2001 (31)	62	6	96	70	68†	No hysterectomy; fibroid expulsion (<i>n</i> = 2); Endometritis (<i>n</i> = 1)
Spies et al, 2001 (32)	200	21	86* 88† 90‡	93* 93† 91‡	42* 60†	No hysterectomy endometrial infection (<i>n</i> = 2); fibroid expulsion (<i>n</i> = 1); pulmonary embolus (<i>n</i> = 1); DVT (<i>n</i> = 1)
Katsumori et al, 2002 (33)	60	-	98 100‡	97 100‡	55 70‡	No hysterectomy fibroid expulsion (<i>n</i> = 2); amenorrhea (<i>n</i> = 1)
Walker and Pelage, 2002 (34)	400	16.7	84	79	64 (MR) 73 (US)	Hysterectomy for infection (<i>n</i> = 3); amenorrhea (<i>n</i> = 26); fibroid expulsion (<i>n</i> = 9); chronic vaginal discharge (<i>n</i> = 13)
Pron et al 2003 (35)	538	3	83	77	42	Amenorrhea (<i>n</i> = 21)

Note.—DVT = deep vein thrombosis. * 3 months, † 6 months, ‡ 1 year, § 2 months, || 4 months.

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The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.