# Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomas

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**Abbreviations:** FIBROID = Fibroid Registry for Outcomes Data, UAE = uterine artery embolization

## PREAMBLE

THE membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both 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, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

## METHODOLOGY

SIR produces its Standards of Practice documents 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 depending upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then a critical review of peer-reviewed articles is performed with regards to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, 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 using a modified Delphi Consensus Method (Appendix A) (1,2). 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 Revisions Subcommittee members of the Standards of Practice Committee, 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 Subcommittee, and appropriate revisions are made to create the finished standards document. Prior to its publication, the document is endorsed by the SIR Executive Council.

## INTRODUCTION

This guideline was revised from a joint quality improvement document initially developed by SIR in collaboration with the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) for the performance of uterine artery embolization (UAE) for management of symptomatic leiomyomas.

Throughout this document, the procedure under discussion will be referred to as UAE for symptomatic leiomyomas. 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 treatment of uterine leiomyomas 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 obstetrical emergencies, such

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**Table 1**
**Outcomes of UAE for Uterine Leiomyomas (5,7–21)**

| Study, Year | Study Type | No. of Pts. | Follow-up | Outcome |
|---|---|---|---|---|
| Goodwin et al, 2008 (5), FIBROID Registry | PMC | 1,916 in study; 1,287 finished survey | 36 mo | Symptom improvement: SSS 41.41 points, HRQOL 41.47 points; most improvement in both scores at 3 y |
| Lohle et al, 2008 (7) | Prospective | 93 | 54 mo | Symptom improvement: bleeding 97%, pain 93%, bulk symptoms 92% |
| Hehenkamp et al, 2005 and 2008 (8,9), EMMY | RCT | 156; UAE 81, hys 75 | 24 mo | Equally significant improvement in HRQOL; UAE group-UV decrease 48% |
| Volkers et al, 2007 (10), EMMY | RCT | 156; UAE 81, hys 75 | 24 mo | Moderate or greater improvement: pain, UAE 85%, hys 78%; bulk symptoms, UAE 66%, hys 69%; UAE group-UV decrease 48%, DFV decrease 61% |
| REST Investigators, 2007 (11) | RCT | 157; UAE 106, hys 43, myo 8 | 12 mo | No significant differences between groups in responses to outcome questionnaire |
| Dutton et al, 2007 (12), HOPEFUL | RMCT | 1,108; UAE 649, hys 459 | UAE 4.6 y; hys 8.6 y | Relief of symptoms: UAE 85%, hys 99% |
| Gabriel-Cox et al, 2007 (13) | Retrospective | 562; bilateral UAE 529, unilateral UAE 33 | 5 y | NR |
| Goodwin et al, 2006 (14) | PMC | 209; UAE 149, myo 60 | UAE 1y; all pts 6 mo | Equally significant improvement in UFQOL, QOL, menstrual bleeding scores; UAE group-UV decrease 39%, DFV decrease 54% |
| Siskin et al, 2006 (15) | PMC | 146; UAE 77, myo 69§ | UAE 2 y; all pts 6 mo | Equally significant improvement, UFQOL and bleeding scores at 6 mo; UAE group-median QOL scores significantly higher at 6 mo; sustained at 12 and 24 mo; UV decrease 33%, DFV decrease 54% |
| Bucek et al, 2006 (16) | Retrospective | 53 | 3 y | Relative reduction in symptoms: bleeding 81%, pain 82%, bulk 79%, urinary 60%, sexual dysfunction 71% |
| Scheurig et al, 2006 (17) | Prospective | 71 | Two groups: short, 5 mo; long, 14 mo | SSS decreased significantly in both groups; HRQOL increased significantly in both groups; UV decrease 36%, DFV decrease 66% |
| Smeets et al, 2006 (18) | Prospective | 110 | 14 mo | Improvement/resolution: menorrhagia 79%, dysmenorrhea 70%, pain 78% |
| Walker et al, 2006 (19) | Prospective | 172 | 5–7 y | Improvement/resolution: menorrhagia 75%, constipation 66%; sexual function: no change 53%, improved 26%, worsened 10% due to pain or discharge |
| Joffre et al, 2004 (20), FEMIC | PMC | 85 | 16 mo | Menorrhagia improvement 84%; DFV decrease 72.5% |
| Smith et al, 2004 (21) | Retrospective | 79 | 32 mo | Improvement: SSS 35.19 points, HRQOL 35.66 points, sexual function 30.11 points; UV decrease 40.7% |

Note.— AE = adverse event; DFV = dominant fibroid volume; ED = emergency department; FRQOL = fibroid-related quality of life; HRQOL = health-related quality of life; hys = hysterectomy; myo = myomectomy; PES = postembolization syndrome; PMC = prospective multicenter; pts = patients; QOL = quality of life; NR = not reported; RCT = randomized control trial; SSS = symptom severity score; UFQOL = uterine fibroid quality of life; UV = uterine volume.
* Spies et al, 2005.
† Worthington-Kirsch et al, 2005.
‡ Complication reported in 2005.
§ Myomectomy group is the same group as reported in Goodwin et al (14), 2006.
‖ Statistically significant.

| Additional Treatment | Complications | Patient Satisfaction |
|---|---|---|
| Hys 10%, myo 3%, repeat UAE 2% | Amenorrhea: overall 28.6%; age < 40 y 1.6%; unplanned ED visit: 6 mo 6%; 12 mo 3%*; AEs during hospitalization 94†; pain after discharge requiring readmission 2.1% | 86% |
| Hys 12%, myo 4%, repeat UAE 9% | Amenorrhea 33%, leiomyoma expulsion 12%, transient vaginal discharge 17% | 90% |
| Hys after UAE 24% | At 6 wks‡: UAE-minor 64.2%, major 4.9%; hys-minor 56%, major 2.7%; UAE complications-readmission 11%, vaginal discharge 21%, leiomyoma expulsion 14.8%, hot flashes 19.8% | Hys > UAE only because fewer UAE patients were "very satisfied" |
| After UAE: hys 24%, hysteroscopy 2% | UAE group-amenorrhea at 2 yrs 37% | NR |
| Hys after UAE or repeat UAE 20% | UAE: minor 34%, major 15%; surgery: minor 20%, major 20% | UAE 88%, surgery 93% |
| UAE group: hys 11%; myo 5%; repeat UAE 5% | UAE group 19%‖: vaginal discharge 13%, leiomyoma expulsion 8%, septicemia requiring emergent surgery 3%, amenorrhea: age > 40 y 1.4%; age < 40 y 0.2%; hys 26% | UAE 91%, hys 86% |
| Hys 18%, myo 3%, repeat UAE 2%, endometrial ablation 2% | ED admissions 10% (pain most common complaint); hys for infection 0.1%; leiomyosarcoma diagnosed after UAE 0.3% | NR |
| UAE group: hys 1%, myo 0.5% | UAE 22%‖; myo 40% | UAE 81%, myo 75% |
| UAE group: hys 4%, repeat UAE 3%, drug therapy 3%, endometrial ablation 1% | UAE 26%: ≥1 AE (all minor) at 6 mo; amenorrhea 3%; chronic vaginal discharge 1.6%; myo 42%: 2 major complaints | NR |
| Hys 7.5% | Amenorrhea 7.5% | 95% |
| Repeat UAE 7%, hys 3% | Leiomyoma expulsion 3%; amenorrhea 4%: (< 45 y/o 1%) | NR |
| Hys or repeat UAE 9% | Vaginal discharge (new or increased) 13%; leiomyoma expulsion 4%; amenorrhea 3% (all age > 45 y) | 78% |
| Hys 5%, myo 3%, hysteroscopic myo 5% | Persistent vaginal discharge 5%; leiomyoma expulsion 34% | 87% |
| Hys 9% | Delayed PES 7%; delayed leiomyoma expulsion 2%; amenorrhea 4% | NR |
| Hys 15%, myo 5%, repeat UAE 1% | Readmission for pain or fever < 1 week after UAE 14% | 80% |

**Table 2**
**Results of UAE in Cases of Adenomyosis with or without Uterine Leiomyomas (24,25,27,28)**

| Study, Year | Study Type | Patients | Follow-up |
|---|---|---|---|
| Kim et al, 2007 (24) | Retrospective | 54, adenomyosis only | 5 y |
| Lohle et al, 2007 (25) | Prospective | 38 patients in three groups: adenomyosis only (A), dominant adenomyosis/leiomyomas (B), dominant leiomyomas/adenomyosis (C) | 18 mo |
| Pelage et al, 2005 (27) | Prospective | 18, adenomyosis only: 14 diffuse, 4 focal | Up to 24 mo |
| Kim et al, 2003 (28) | Retrospective | 43, adenomyosis only | 4 mo |

Note.—DFV = dominant fibroid volume; hys = hysterectomy; UV = uterine volume.

as postpartum hemorrhage. Goodwin et al (4) reported the first experience in the United States of treating leiomyomas with UAE in 1997. Since those initial reports, UAE has become a widely accepted alternative to hysterectomy and myomectomy, with approximately 25,000 UAE procedures performed annually worldwide (5).

A landmark registry in this field, the Fibroid Registry for Outcomes Data (FIBROID), was created in 1999 and has played a significant role in establishing UAE as a viable alternative to hysterectomy. The structure of the registry has been described in detail (6), and 3-year outcomes for almost 2,000 patients have now been reported (5). The findings of the FIBROID Registry demonstrate that UAE results in a durable improvement in quality of life when performed by an experienced interventional radiologist in an academic center or in a community practice (5).

The 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, with few complications and very good outcomes (5,7–21). **Table 1** provides details of UAE trials and outcomes.

These guidelines are written to be used in quality improvement programs to assess UAE procedures. The most important processes of care are (i) selecting the patient, (ii) performing the procedure, and (iii) monitoring the patient. The outcome measures or indicators for these processes are indications for the procedure, success rates, and complication rates. Outcome measures are assigned threshold levels.

## DEFINITIONS

UAE is defined as the delivery of an embolic agent, typically tris-acryl gelatin microspheres or spherical polyvinyl alcohol, via a catheter or microcatheter placed in both uterine arteries. The goal of UAE is to occlude or markedly reduce uterine blood flow at the arteriolar level, producing irreversible ischemic injury to leiomyomas while avoiding permanent damage to the uterus.

*Technical success* is defined as occlusion or marked reduction in blood flow in both uterine arteries. Successful embolization of only one uterine artery is 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 leiomyomas has failed to occur (best confirmed by contrast-enhanced magnetic resonance [MR] imaging).

*Clinical success* is defined as the significant improvement or 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 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.

The *Uterine Fibroid Symptom and Health-related Quality of Life Questionnaire* is a disease-specific questionnaire that was developed as part of the FIBROID Registry (6) and is a helpful tool for evaluating the severity of uterine leiomyoma symptoms before and after UAE (22).

*Menorrhagia* is defined as heavy, prolonged menstrual flow that may result in chronic blood loss or anemia. Submucosal leiomyomas are more likely to cause menorrhagia than leiomyomas in other locations, although large intramural leiomyomas that distort the endometrial cavity may also cause heavy bleeding (23).

*Dysmenorrhea* is defined as painful menstruation.

| Outcomes | Complications/Additional Treatment |
|---|---|
| 4 immediate treatment failures; recurrent symptoms in 38% of 50 pts. with short-term success; UV decreased 27%; satisfaction rate 65% | Amenorrhea: immediate 4%, overall 18%, 10% hys for recurrent symptoms |
| UV decreased 45%; DFV decreased 80%; no difference between groups in symptomatic improvement, additional surgery, or complication rates; satisfaction rates by group: A 83%; B 75%; C 50% | Permanent amenorrhea 16%; transient amenorrhea 32%; spontaneous leiomyoma expulsion 16%; hys 13%; adenomyosis resection 3% |
| Resolution of abnormal bleeding 56%; improvement in pelvic pain and pressure 50% | 44% required additional treatment including hys 28%, medical therapy, or endometrial ablation |
| Improvement: menorrhagia 95%; dysmenorrhea 95%; pelvic heaviness 78%; urinary frequency 48%; satisfaction rate 93% | Permanent amenorrhea 2% |

*Adenomyosis* is defined as implants of endometrial tissue within the uterine wall that cause progressive dysmenorrhea and menorrhagia. Adenomyosis and leiomyomas frequently coexist and are best distinguished from one another with MR imaging (7).

*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 leiomyomas as a result of (i) colonization of devitalized leiomyoma tissue by bloodborne 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 leiomyomas 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 passage, 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.

## QUALITY IMPROVEMENT

While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, 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 fall 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 should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for 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. Thus, 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 (Appendix B). The complication rates and thresholds described here refer to major complications unless otherwise specified.

**Table 3**
**Reproductive Outcomes in Studies of UAE and Other Treatments for Uterine Leiomyomas (30–38)**

| Study, Year | Study Type | Patients | Objective |
|---|---|---|---|
| Mara et al, 2008 (30) | RCT | UAE (58); myo (63) | Pregnancy outcomes after UAE vs myo |
| Usadi et al, 2007 (31) | Review | — | Pregnancy outcomes after UAE |
| Holub et al, 2006 (32) | PCC | UAE (112); LUAO (225) | Pregnancy outcomes after LUAO vs UAE |
| Goldberg et al, 2006 (33) | Review | — | Pregnancy outcomes after UAE vs myo |
| Walker et al, 2006 (34) | Retrospective | 1,200 | Pregnancy outcomes after UAE |
| Pron et al, 2005 (35) | MRCT | 555 | Pregnancy outcomes after UAE |
| Carpenter et al, 2005 (36) | Prospective | 671 | Pregnancy outcomes after UAE |
| Kim et al, 2005 (37) | Prospective | 94 | Pregnancy outcomes after UAE |
| Goldberg et al, 2004 (38) | Metaanalysis | UAE (53); LM (139) | Pregnancy outcomes after UAE vs LM |

Note.—EA = elective abortion; IVF = in vitro fertilization; LM = laparoscopic myomectomy; LUAO = laparoscopic uterine artery occlusion; MRCT = multicenter randomized controlled trial; myo = myomectomy; PCC = prospective cohort controlled; PPH = postpartum hemorrhage; RCT = randomized controlled trial; SAB = spontaneous abortion; SGA = small for gestational age.

## INDICATIONS AND CONTRAINDICATIONS

### Indications

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

UAE is indicated for the treatment of uterine leiomyomas that are causing significant symptoms, specifically menstrual bleeding that is prolonged or is causing anemia, severe menstrual cramping, and/or bulk symptoms including pelvic pressure, urinary frequency, and constipation. More than 95% of UAE procedures should be performed for these appropriate indications.

Adenomyosis may also cause menorrhagia or dysmenorrhea and often coexists with fibroid disease. Although adenomyosis may not respond to UAE, a few studies have reported durable improvement in symptoms in 50%–70% of patients with adenomyosis alone or coexistent adenomyosis and leiomyomas (24,25). Although additional treatment, typically hysterectomy, may be required for recurrent symptoms in as many as 50% of patients with adenomyosis within 3 years after embolization, UAE still represents a reasonable option in this subset of patients, especially those who desire fertility, are at increased risk in the setting of surgery, or absolutely desire uterine preservation (26). **Table 2** (24,25,27,28) provides details of UAE trials in patients with adenomyosis with or without uterine leiomyomas.

### Contraindications

In general, the relative contraindications to UAE are the same as those for other angiographic procedures, including coagulopathy, severe contrast allergy, and renal impairment. There are other relative contraindications, however, that are more specific to UAE. Any prior treatment or procedure that could alter pelvic arterial anatomy, such as salpingo-oophorectomy, resection of an ectopic pregnancy, or pelvic irradiation, may make selection and embolization of the uterine arteries difficult or impossible. Concurrent use of a gonadotropin-releasing agonist may cause diffuse vasospasm, which may impact the technical success of the procedure.

The size and location of the leiomyomata should also be considered. Enlargement of the uterus to greater than the equivalent of 20 to 24 weeks gestation may make adequate embolization difficult to accomplish. A pedunculated (base < 50% of diameter) subserosal or

| Pregnancies | Outcomes | Conclusions |
|---|---|---|
| Myo, 33 (40 trying); UAE, 19 (26 trying) | Myo: 19 labor, 5 still pregnant, 6 SAB; UAE: 5 labor, 1 still pregnant, 9 SAB | 60% SAB after UAE significantly higher than previously reported rate of 23% |
| — | — | Myomectomy remains the standard of care for preservation of fertility |
| LUAO, 38; UAE, 20 | SAB: UAE 56%; LUAO, 10.5% | Significantly increased risk of SAB, malpresentation and Cesarean section after UAE; no significant difference in preterm delivery |
| — | Higher rates of preterm delivery, SAB, abnormal placentation and PPH after UAE | Most pregnancies after UAE have good outcomes, but myo is the treatment of choice in most patients desiring fertility |
| 56 (108 trying) | 60% successful term pregnancy, 18% premature, 73% Cesarean section (majority elective); 18% PPH; 30% miscarriage, 5% EA, 3% stillborn, 2% ectopic | Significant increase in Cesarean section and higher rates of preterm delivery, PPH and miscarriage after UAE compared with the general obstetric population |
| 24 (1 IVF) | 75% live birth, 17% SAB, 8% EA; 78% full term (50% Cesarean section); 17% abnormal placentation, 17% PPH, 22% SGA | Close monitoring of placental status recommended |
| 29 | 55% live birth, 27% miscarriage, 7% EA, 3% ectopic; 68% full term (89% Cesarean section); 20% PPH, 6% SGA | Increased rate of Cesarean section after UAE |
| 8 | 88% live birth, 12% EA; 86% full term (29% elective Cesarean section) | — |
| All | SAB: UAE 24%, LM 15%; PPH: UAE 6%, LM 1%; preterm delivery: UAE 16%, LM 3%; Cesarean section: UAE 63%, LM 59%; SGA: UAE 5%, LM 8% | Significantly increased risk of SAB, PPH, preterm delivery and malpresentation after UAE |

submucosal leiomyoma may be at risk for detachment from the uterus, a situation that may necessitate surgical intervention. A large submucosal leiomyoma (> 10 cm in diameter) may present an increased risk for infection or prolonged discharge following embolization, and the greater the ratio between the endometrial interface and diameter of a submucosal leiomyoma, the more likely that leiomyoma is to migrate into the endometrial cavity after UAE (29). A large hydrosalpinx, especially in a patient with a history of sexually transmitted disease, may predispose to infection after UAE.

A desire to maintain childbearing potential is a relative contraindication. Although uncomplicated pregnancies and normal deliveries have been reported after UAE (30–38), a recent randomized controlled trial comparing UAE and myomectomy (30) found superior reproductive outcomes after myomectomy in the first 2 years of follow-up. Two reviews of the literature (31,33) came to the same conclusion that myomectomy remains the standard of care for preserving fertility because of the increased risks of spontaneous abortion, preterm delivery, and abnormal placentation after UAE; however, both also stated that UAE should still be considered in patients who are not good candidates for myomectomy and in patients who refuse surgery (31,33). **Table 3** (30–38) details reproductive outcomes after various therapies for uterine leiomyomas, including UAE.

The absolute contraindications to UAE are viable pregnancy, active (ie, untreated) infection, and suspected uterine, cervical, or adnexal malignancy (unless the procedure is being performed for palliation or as an adjunct to surgery).

## SUCCESS RATES AND THRESHOLDS

### 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 (**Table 4**).

### Recurrence

The overall rate of repeat intervention (hysterectomy, myomectomy, or repeat UAE) among patients enrolled in the FIBROID Registry was 14.4% at 3 years (5). Although this implies inadequate treatment of existing leiomyomas, a viable uterus may also give rise to new leiomyomas. For this reason, there are no specific measures that can be recommended to reduce the rate of recurrence. The threshold for recurrence of leiomyoma-related symptoms is at least 15% at 3 years.

The overall success rates of UAE will increase when the interventional radiologist is actively involved in all processes of care from patient selection to peripro-

**Table 4**
**Expected Outcomes of UAE for Uterine Leiomyomas and Adenomyosis**

| Outcome | Reported Rate (%) | Threshold (%) |
|---|---|---|
| UAE for leiomyomas | | |
| Leiomyoma size reduction | 50–60 | 40 |
| Uterine size reduction | 40–50 | 30 |
| Reduction of bulk symptoms | 88–92 | 80 |
| Elimination of abnormal uterine bleeding | > 90 | 85 |
| Successful elimination of symptoms | 75 | 70 |
| Patient satisfaction (would recommend UAE to friend) | 80–90 | 75 |
| UAE for adenomyosis | | |
| Uterine volume reduction | 25–45 | 20 |
| Elimination of abnormal uterine bleeding | 50–95 | 50 |
| Improvement in pelvic pain and pressure | 50–95 | 50 |
| Patient satisfaction | 65–90 | 50 |

**Table 5**
**Complication Incidences and Thresholds for UAE in the Treatment of Uterine Leiomyomas**

| Complication | Reported Rate (%) | Suggested Threshold (%) |
|---|---|---|
| Permanent amenorrhea | | |
| Age < 45 y | 0–3 | 3 |
| Age > 45 y | 20–40 | 45 |
| Prolonged vaginal discharge | 2–17 | 20 |
| Transcervical leiomyoma expulsion | 3–15 | 15 |
| Septicemia | 1–3 | 3 |
| Deep vein thrombosis/pulmonary embolus | < 1 | 2 |
| Nontarget embolization | < 1 | < 1 |

cedural management of the patient to long-term monitoring of outcomes.

### Complication Rates and Thresholds

The most commonly reported complications of UAE are permanent amenorrhea and prolonged vaginal discharge. Less commonly reported complications include delayed expulsion of leiomyoma tissue, prolonged or poorly controlled pain, infection (pyomyoma, endometritis, or tuboovarian abscess), urinary tract infection or urinary retention, and vessel or nerve injury at the access site (**Table 5**). Reported but rare major complications include death secondary to sepsis or pulmonary embolism, inadvertent embolization of a leiomyosarcoma, uterine necrosis, buttock necrosis, labial necrosis, vesicouterine fistula formation, small bowel volvulus, and acute renal failure (39–49).

Several studies include postembolization syndrome as a minor complication, although it has been defined as an expected aspect of recovery. When the typical symptoms of postembolization syndrome are persistent or severe enough to require readmission to the hospital or reintervention, it should be classified as a minor or major complication depending on the length of hospitalization or the type of intervention required.

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 (50). Transient amenorrhea after UAE is usually limited to a few cycles (50) and is not considered a major complication. Permanent amenorrhea has been reported to occur in as many as 37% of patients at 2 years (10), but this has been associated with increasing age, as it occurs much more frequently in women older than 45 years at the time of the procedure (51,52). Permanent amenorrhea is classified as a major complication (ie, permanent adverse sequela), although some patients may not view it as such.

Although sexual dysfunction has been described after UAE (53), the few studies that specifically address this topic conclude that sexual function improves in the majority of patients (54–56). In a randomized trial comparing UAE versus hysterectomy, sexual functioning and body image scores improved in both groups but only significantly so after UAE (54).

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 (57); however, the radiation dose should be kept as low as possible to avoid injuries such as skin burns and ovarian dysfunction. Specific measures to document and decrease radiation dose, including limiting the use of angiographic runs, magnified views, and oblique views, have been described in the SIR Guidelines for Patient Radiation Dose Management (58). Aortography has been shown to contribute more than 20% of the total radiation dose for UAE even though it identifies substantial collateral ovarian flow in fewer than 1% of patients (59); therefore, selective rather than routine use of aortography should be considered.

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 larger volume than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed here. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient series (eg, early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program. In **Table 5**, all values are supported by the weight of literature evidence and panel consensus.

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## APPENDIX A: CONSENSUS METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. 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.

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

## APPENDIX B: SIR STANDARDS OF PRACTICE COMMITTEE CLASSIFICATION OF COMPLICATIONS BY OUTCOME

### Minor Complications

A. No therapy, no consequence.
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. Permanent adverse sequelae.
F. Death.

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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 towards 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.