

Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomata

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ABBREVIATIONS

FIBROID = Fibroid Registry for Outcomes Data, GnRH = gonadotropin-releasing hormone, 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 dependent 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 regard 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

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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 the 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 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 made to create the finished standards document. Prior to its publication the document is endorsed by the SIR Executive Council.

INTRODUCTION

The majority of the work in this document is based on the 2010 Quality Improvement Guidelines for Uterine Artery Embolization [UAE] for Symptomatic Uterine Leiomyomata (3). For this update, the relevant literature was reviewed and has resulted in revisions to recommendations on UAE as a treatment in specific circumstances, including in the setting of previous medical management of leiomyomas, for adenomyosis, pedunculated leiomyomas, and for women who wish to retain future fertility. This update also includes recommendations for counseling of patients who are being considered for treatment of these conditions.

Throughout this document, the procedure under discussion will be referred to as 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. UAE is a widely accepted alternative to hysterectomy and myomectomy, with approximately 25,000 UAE procedures performed annually worldwide (4).

Medical therapy has a very limited role for managing symptomatic leiomyomata, and, at this time, there are no accepted medical therapies suitable for long-term use. Administration of gonadotropin-releasing hormone (GnRH) agonists results in creation of a hypoestrogenic state and can induce leiomyomata size regression and control some of the symptoms that are caused by uterine leiomyomata. Side effects are common, however, and include hot flashes, sleep disturbance, vaginal dryness, mood changes, and loss of bone mineral density, the latter of which limits GnRH agonist use to a temporary therapy of typically 3–6 months duration (5–7). Although add-back medication with progestogen, tibolone, estrogen/progestogen combinations, and raloxifene has been studied, scientific evidence is insufficient to recommend the use of these agents for long-term medical therapy for

the treatment of symptomatic leiomyomata at this time (6,7). The use of aromatase inhibitors and intrauterine levonorgestrel systems has similarly not been endorsed in the gynecology literature because of a lack of adequate scientific data. The potential of other promising hormonal therapies such as progesterone antagonists (mifepristone, asoprisnil), modified progestogens (danazol), and antiprogestins (gestrinone) is limited by preventing reproduction (6).

As such, the role of medical therapy is currently limited to achieving short-term symptom control with GnRH agonists before definitive therapy can be performed surgically or by UAE. Although GnRH agonist use before the performance of UAE may complicate the procedure by induction of vasospasm, such a sequential therapeutic protocol has been employed successfully and has been reported in the literature (8).

Transcatheter embolization of the uterine arteries for treatment of uterine leiomyomata was first reported by Ravina et al in 1995 (9). The procedure was based on established techniques for treating pelvic bleeding related to trauma or gynecologic emergencies, such as postpartum hemorrhage. Goodwin et al (10) reported the first experience in the United States of the treatment of leiomyomata with UAE in 1997.

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 (11), and 3-year outcomes for almost 2,000 patients have now been reported (4). The findings of FIBROID demonstrate that UAE results in a durable improvement in quality of life when performed by an experienced interventional radiologist in an academic center or a community practice (4).

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 (Table 1) (4,12–26).

After nearly two decades of clinical investigation of UAE as a treatment for leiomyomas and, more recently, adenomyosis, including data from randomized trials reporting long-term outcomes similar to those for surgical therapies, it is clear that UAE is appropriate for nearly all patients considering treatment. Given its minimally invasive nature, established favorable cost profile, and associated rapid recovery and return to work, UAE should be considered a front-line therapy for leiomyomata and should therefore be presented to all patients as an option for these conditions, with referral for consultation to a qualified interventional radiologist for those wishing to determine if they are suitable candidates for treatment.

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

DEFINITIONS

Adenomyosis is defined as implants of endometrial tissue within the uterine wall that may cause progressive dysmenorrhea and menorrhagia. Adenomyosis and leiomyomata frequently coexist and are best distinguished from one another with 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.

Dysmenorrhea is defined as painful menstruation.

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 usually associated with the ascent of vaginal organisms into the endometrium, 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.

Menorrhagia is defined as heavy, prolonged menstrual flow that may result in chronic blood-loss anemia. Menorrhagia is most commonly caused by submucosal leiomyomas but may also be caused by intramural leiomyomas that distort the endometrial cavity.

Myometrial infection is defined as infection of the nonleiomyoma uterine muscle, 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 antibiotic agents and medications to reduce pain and inflammation, but, ultimately, surgical management may be necessary.

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/or 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 ischemic infarction of the myoma. This process should not be considered a complication of UAE unless unplanned medical therapy or prolonged hospitalization is required.

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.

Technical success is defined as occlusion of arterial supply to the leiomyomata, usually requiring bilateral UAE. On occasion, a single uterine artery may supply all the blood flow to the leiomyomata, and, in this circumstance, embolization of that one uterine artery is considered a technical success. Occlusion of the arterial supply results in infarction of the leiomyomata, which may be confirmed by demonstrating absence of perfusion of them on contrast-enhanced MR imaging examination.

Transcervical leiomyoma expulsion is defined as detachment of leiomyoma tissue from the uterine wall and subsequent transvaginal passage, most commonly occurring with submucosal leiomyomata. 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.

UAE is defined as the delivery of an embolic agent via a catheter or microcatheter placed in both uterine arteries. The goal of UAE is to cause infarction of the leiomyomata while avoiding permanent damage to the uterus.

The *Uterine Fibroid Symptom and Health-related Quality of Life* questionnaire is a validated disease-specific symptom and quality-of-life questionnaire that was used in FIBROID and many other studies. It is intended as a tool to determine the status of symptoms and quality of life before and after leiomyoma therapies (27).

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 here refer to major complications unless otherwise specified.

Table 1 . Outcomes of UAE for Uterine Leiomyomas (4,12–28)

Study, Year	Type	No. of Pts.	Follow-up	Outcome	Additional Treatment	Complications	Patient Satisfaction
Goodwin et al (4), 2008	PMC	1,916 (1,287 finished survey)	36 mo	Symptom improvement: SSS, 41.41 points; HRQOL, 41.47 points; most improvement in both scores at 3 y	Hys (10%), myo (3%), repeat UAE (2%)	Amenorrhea, overall (28.6%), age < 40 y (1.6%); unplanned ER visit,* 6 mo (6%); 12 mo (3%); AEs during hospitalization† (n = 94); pain after discharge requiring readmission (2.1%)	86%
Lohle et al (12), 2008	Prospective	93	54 mo	Symptom improvement: bleeding (97%), pain (93%), bulk symptoms (92%)	Major interventions: 1 y (11%), overall (25%), hys (12%), myo (4%), repeat UAE (9%)	Amenorrhea (33%), leiomyoma expulsion (12%), transient vaginal discharge (17%)	90%
Hehenkamp et al (13,14), 2008 and 2005‡	RCT	156 (UAE, hys)	24 mo	Equally significant improvement in HRQOL; UAE group UV decrease (48%)	Hys after UAE (24%)	Overall (6 wk): 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 because fewer in UAE group “very satisfied”
Volkers et al (15), 2007	RCT	156: UAE (81), hys (75)	24 mo	Moderate or greater improvement; pain, UAE (85%), hys (78%); bulk, UAE (66%), hys (69%); UAE group, UV decrease (48%), DFV decrease (61%)	Post-UAE hys (24%), hysteroscopy (2%)	UAE group: amenorrhea at 2 y (37%)	NR
REST Investigators (16), 2007, REST	RCT	157: UAE (106), hys (43), myo (8)	12 mo	No significant differences between groups in responses to outcome questionnaire	Hys after UAE or repeat UAE (20%)	UAE: minor (34%); major (15%); surgery, minor (20%); major (20%)	UAE (88%), surgery (93%)
Dutton et al (17), 2007	RMCT	1,108: UAE (649), hys (459)	UAE, 4.6 y; hys, 8.6 y	Relief of symptoms: UAE (85%), hys (99%)	UAE group (18%), 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	UAE (91%), hys (86%)

(Continued)

Table 1. Outcomes of UAE for Uterine Leiomyomas (4,12–28) (continued)

Study, Year	Type	No. of Pts.	Follow-up	Outcome	Additional Treatment	Complications (1.4%); age < 40 y (0.2%); hys (26%)	Patient Satisfaction
Gabriel-Cox et al (18), 2007	Retrospective	562: bilateral UAE (529), unilateral UAE (33)	5 y	NR	Hys (18%), myo (3%), repeat UAE (2%), endometrial ablation (2%)	ER admissions (10%); pain most common complaint, hys for infection (0.1%), leiomyosarcoma diagnosed after UAE (0.3%)	NR
Goodwin et al (19), 2006	PMC	209: UAE (149), myo (60)	UAE, 1 y; all pts., 6 mo	Equally significant improvement: UFQOL, QOL, menstrual bleeding scores; UAE group, UV decrease (39%), DFV decrease (54%)	UAE group: hys (1%), myo (0.5%)	UAE (22%) [§] , myo (40%); no patients developed amenorrhea	UAE (81%), myo (75%)
Siskin et al (20), 2006	PMC	146: UAE (77), myo (69)	UAE, 2 y; all pts., 6 mo	Equally significant improvement in 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%)	UAE group: hys (4%), repeat UAE (3%), drug therapy (3%), endometrial ablation (1%)	UAE (26%): at least 1 AE (all minor) at 6 mo; amenorrhea (3%), chronic vaginal discharge (1.6%), myo (42%), 2 major	NR
Bucek et al (21), 2006	Retrospective	53	3 y	Relative reduction in symptoms: bleeding (81%), pain (82%), bulk (79%), urinary (60%), sexual dysfunction (71%)	Hys (7.5%)	Amenorrhea (7.5%)	95%
Scheurig et al (22), 2006	Prospective	71	2 groups, short: 5 mo, long: 14 mo	SSS decreased and HRQOL increased significantly in both groups; UV decrease (36%), DFV decrease (66%)	Repeat UAE (7%), hys (3%)	Leiomyoma expulsion (3%), amenorrhea (4%), age < 45 y (1%)	NR
Smeets et al (23), 2006	Prospective	110	14 mo	Improvement/resolution: menorrhagia (79%), dysmenorrhea (70%), pain (78%)	Hys or repeat UAE (9%)	Vaginal discharge, new or worse (13%); leiomyoma expulsion (4%); amenorrhea (3%), all age > 45 y	78%
Walker et al (24), 2006	Prospective	172	5–7 y	Improvement/resolution: menorrhagia (75%), constipation (66%), sexual function, no change (53%),	Additional intervention (13%), hys (5%), myo (3%), hysteroscopic myo (5%)	Persistent vaginal discharge (5%), leiomyoma expulsion (34%)	87%

(Continued)

Table 1. Outcomes of UAE for Uterine Leiomyomas (4,12–28) (continued)

Study, Year	Type	No. of Pts.	Follow-up	Outcome	Additional Treatment	Complications	Patient Satisfaction
Joffe et al (25), 2004	PMC	85	16 mo	improved (26%), worsened (10%) due to pain or discharge Menorrhagia improvement (84%), DFV decrease (72.5%)	Hys (9%)	Delayed PES (7%), delayed leiomyoma expulsion (2%), amenorrhea (4%)	NR
Smith et al (26), 2004	Retrospective	79	32 mo	Improvement: SSS, 35.19 points; HROOL, 35.66 points; sexual function, 30.11 points; UV decrease (40.7%)	Additional intervention (22%), hys (15%), myo (5%), repeat UAE (1%)	Readmission for pain or fever < 1 wk after UAE (14%)	80%

AE = adverse event, DFV = dominant fibroid volume, ER = emergency room, HROOL = health-related quality of life, hys = hysterectomy, myo = myomectomy, NR = not reported, PES = postembolization syndrome, PMC = prospective multicenter, pts. = patients, QOL = quality of life, RCT = randomized controlled trial, REST = Randomized Trial of Embolization versus Surgical Treatment for Fibroids, SSS = symptom severity score, UAE = uterine artery embolization, UFQOL = uterine fibroid quality of life, UV = uterine volume.

*Spies et al (28), 2005.

[†]Worthington-Kirsch et al (29), 2005.

[‡]Complications reported in 2005.

[§]Statistically significant.

^{||}Myomectomy group is the same group as reported by Goodwin et al (19), 2006.

INDICATIONS AND CONTRAINDICATIONS

Indications

Patient selection for UAE requires consideration of presenting symptoms, clinical history, physical examination, size number and location of the leiomyomata or other uterine conditions, patient interest in future fertility, and patient preferences. Although each patient's circumstances must be taken into consideration when recommending therapy, practical guidelines can be adopted that allow for an appropriate standard of care to ensure proper patient selection.

UAE is indicated for the treatment of uterine leiomyomata that are causing significant symptoms, occasionally a single symptom, but more commonly a combination of symptoms. The most common of these are:

1. Heavy or prolonged menstrual bleeding;
2. Severe menstrual cramping;
3. Pelvic pressure, discomfort, excessive bloating or fullness, particularly perimenstrual, or bothersome abdominal wall distortion caused by the enlarged uterus;
4. Pelvic pain related to identified leiomyomas, including dyspareunia;
5. Urinary urgency, frequency, nocturia, or retention related to the enlarged leiomyomatous uterus; and
6. Hydronephrosis caused by the enlarged uterus.

The recommended threshold is 95% for the treatment of leiomyomata.

The following are special circumstances for which new recommendations can be made based on a review of the current published literature.

UAE and Adenomyosis

Adenomyosis may cause menorrhagia or dysmenorrhea in a pattern very similar to leiomyomas and is often misdiagnosed as leiomyomata on clinical or ultrasound imaging. It often coexists with leiomyomata. Popovic et al (30) published a review on the treatment of adenomyosis with UAE that included all relevant studies from 1999 to 2010. In the authors' analysis, short-term symptomatic relief for women with pure adenomyosis or adenomyosis with coexistent leiomyomas ranged from 83.3% to 92.9%, and long-term symptomatic relief ranged from 64.5% to 82.4%, with the caveats that none of the studies reviewed constituted level I data and the embolization techniques were variable across the studies (30). Several mid- to long-term retrospective studies have addressed the efficacy of UAE in patients with adenomyosis only and adenomyosis with coexistent leiomyomas (Table 2) (31–34). Overall symptomatic relief ranged from 72.5% to 94% (32,33). In addition, a nonrandomized prospective study in patients with pure adenomyosis demonstrated substantial symptomatic relief (34). This study and another study (35) suggested that MR signal intensity of adenomyosis on preprocedure evaluation may help to stratify women who show a response to treatment with UAE (34,35). Although larger and more rigorous randomized controlled studies in the evaluation of uterine embolization for this condition are warranted, the same is true of all other uterine-sparing therapies that have been used for this condition.

Therefore, in the absence of definitive data demonstrating a clear superiority of one treatment over another, and the current literature showing durable improvement in the large majority of patients treated with embolization, uterine embolization should be considered an appropriate option for patients with symptomatic adenomyosis.

UAE and Pedunculated Subserosal Leiomyomas

Pedunculated subserosal leiomyomas (defined as a stalked, subserosal leiomyoma with stalk diameter < 50% of the leiomyoma's greatest diameter) have been considered potential contraindications to UAE based on an early case report (36) describing postembolization necrosis of the leiomyoma stalk with its detachment into the pelvis, which required hysterectomy. Several recent studies have specifically

Table 2. Results of UAE in Cases of Adenomyosis with or without Uterine Leiomyomas (31–34)

Study, Year	Study Type	No. of Patients	Follow-up	Outcomes	Complications/ Additional Treatment
Froeling et al (31), 2012	Retrospective	40, patients in three groups: adenomyosis only (A), dominant adenomyosis and uterine leiomyomas (B), dominant uterine leiomyomas and adenomyosis (C)	Median 40 mo	Symptomatic control in 29 of 40 (72.5%), best symptomatic improvement and QOL scores seen in C, followed by B, then A	11 treatment failures went on to hysterectomy or dilation and curettage
Liang et al (32), 2012	Retrospective	76, subset of 17 (29%): 6 had adenomyosis only; 11 had adenomyosis and coexistent leiomyomas	Up to 24 mo	Primary success rate 16 of 17 (94%, happy or very happy)	1 of 17 required repeat UAE at 15 mo; secondary success rate (after 1 of 17 with repeat UAE), 17 of 17 (100%)
Smeets et al (33), 2012	Retrospective	40, 18 had adenomyosis only; 22 had adenomyosis and coexistent leiomyomas	Mean 65 mo	29 of 33 (88%) clinically improved (asymptomatic) in those with preserved uteri at 65 mo	7 of 40 (18%) went on to hysterectomy; thickened junctional zone at MR baseline (mean 23 mm) and at 3 mo after UAE (mean 14 mm) associated with treatment failure and hysterectomy
Kim et al (34), 2011	Prospective, nonrandomized	40, adenomyosis only	Up to 18 mo	33 of 40 (82.5%) complete necrosis of adenomyosis	Of 16 patients with complete necrosis who were followed to 18 mo, none had recurrent menorrhagia; 2 had recurrent dysmenorrhea reported as tolerable

MR = magnetic resonance, UAE = uterine artery embolization.

addressed clinical outcomes after UAE in patients with pedunculated leiomyomas (Table 3) (37–40). Katsumori et al (38) and Margau et al (37) reported no evidence of tumor separation or torsion from the uterus in their subset of patients with pedunculated leiomyomas. A greater than 30% postembolization pedunculated subserosal leiomyoma size reduction was seen in two studies (37,39). Toor et al (40), however, did report in their paper that pedunculated subserosal leiomyomas were more common in their cases classified as treatment failures, but the authors conceded that these findings may have been related to the small sample size of the failure group and the methodology that was used for the clinical assessment of UAE success. Moreover, pedunculated subserosal leiomyomas were also seen in those cases determined to be treatment successes. The largest series to date that assessed complications and outcomes of UAE in patients with pedunculated subserosal leiomyomas determined that safe and successful outcomes can be obtained (39), and these conclusions were also stated in two other studies (37,38).

Indeed, the early anecdotal concerns regarding the safety and effectiveness of uterine embolization with pedunculated leiomyomas with a narrow attachment has not been borne out in subsequent larger investigations, and symptomatic and safety outcomes are similar to those in patients without this type of leiomyoma. Therefore, this type of leiomyoma should not be considered a contraindication to uterine embolization.

Fertility and Pregnancy after UAE

Reflecting the caution appropriate for a new intervention, early guidelines from SIR suggested that uterine embolization should not be the first choice for women with symptomatic leiomyomas who wished to become pregnant. There was little evidence to support that caution.

As the procedure developed, some authors began to review the anecdotal outcomes reported in the literature. It was clear from the earliest days of UAE that women could become pregnant and carry pregnancies to term after the procedure. However, there was little evidence to compare pregnancy outcomes after UAE versus those experienced by women after myomectomy or those who had not undergone leiomyoma treatments.

Much of the early literature regarding pregnancy outcomes after UAE came from review of scattered case reports or small retrospective case series. One of the early summaries of those reports was by Goldberg et al (41), and did not provide a comparison group. A subsequent review by the same group (42) compared UAE recipients versus those treated with laparoscopic myomectomy, concluding that those treated with myomectomy had lower odds of preterm labor and malpresentation. A similar review by Homer and Saridogan (43) in 2010 noted increased rates of miscarriage, delivery by caesarean section and postpartum hemorrhage after UAE, but not of preterm labor or malpresentation.

Table 3. Results of UAE in Patients with Pedunculated Subserosal Leiomyomas (37–40)

Study, Year	Study Type	Patients	Follow-up	Outcomes	Complications/ Additional Treatment
Smeets et al (39), 2009	Retrospective	716; 29 with pedunculated subserosal leiomyomas	Mean 30 mo (10–78 mo)	33% mean pedunculated leiomyoma postemboli- zation reduction, 87% mean pedunculated subserosal leiomyoma infarction	No early or late complications
Toor et al (40), 2008	Retrospective	78; 18 with pedun- culated subserosal leiomyomas	15 mo	Reduction in fibroid volume greater in success group (not statistically significant), pedunculated subserosal leiomyomas more common in the failure group ($P <$.03) and volume not decreased as significantly	Clinical failure defined as worsening of symptoms compared to preprocedure; no symptoms improved; patient sought additional treatment due to perceived nonbenefit of UAE
Margau et al (37), 2008	Retrospective	240; 16 with pedunculated subserosal leiomyomas	Up to 12 mo	39.3% average pedunculated subserosal leiomyoma postembolization reduction, nonsignificant change in stalk diameter before and after embolizations	No tumor separation or torsion from uterus, no sepsis
Katsumori et al (38), 2005	Retrospective	196; 12 with pedunculated subserosal leiomyomas	Mean 18.1 mo (5–51 mo)	Complete devascularization of tumors in 11 of 15 (all $>$ 2 cm), no significant change in stalk diameter before and after MRI at 1 y, moderate to marked improvement of bulk-related symptoms in 100%	No tumor separation or torsion from uterus, no infection requiring surgery

MRI = magnetic resonance imaging, UAE = uterine artery embolization.

Mohan et al (44) published the most recent comprehensive review of the published series of malpresentation. These authors noted a higher miscarriage rate after UAE compared with women with untreated leiomyomas, but no differences in the other negative pregnancy outcomes reported in the earlier reviews. The literature is limited in that most of the published studies compare those treated with embolization versus those treated with other interventions. In general, UAE recipients have been older, had multiple earlier interventions (including myomectomies), and likely had more extensive disease than myomectomy recipients. When patients treated with UAE are younger, the rates of pregnancy and complications are more favorable. Pisco et al (45) retrospectively examined the pregnancy outcomes of 72 patients after UAE (nearly 90% were younger than 40 y of age), and found that there were 33 live births among 56 pregnancies (59%), and the rates of spontaneous abortion, preterm labor, caesarean section, and placenta previa were lower than in the largest series of pregnancy outcomes after UAE (46). In a review of 44 women under the age of 40 years who underwent UAE, McLucas (47) reported a 48% pregnancy rate, which is comparable to that seen with myomectomy, and, in those pregnancies, there were no issues with intrauterine growth restriction. However, none of these studies provides sufficient data to definitively guide practice recommendations for patients.

There are reproductive outcomes reported from only one randomized trial comparing embolization to myomectomy (48), published in 2008, with 2-year reproductive outcomes. These results, based

on a randomized group of 121 patients, suggest an advantage for myomectomy over embolization in reproductive outcomes. However, the study allowed a second intervention (myomectomy) for all patients in the uterine embolization group who had a leiomyoma still measuring 5 cm, totaling 26% of the UAE cohort. Thus, this portion of the study group had both interventions under investigation. There also was an unusually high technical failure rate of UAE (11%), much worse than in most series, and nearly two thirds of the myomectomy group—a very high proportion—underwent laparoscopic myomectomy, perhaps affecting the generalizability of the results. Based on the available data from this randomized trial (49), a 2012 Cochrane Review (50) concluded:

There is very low-level evidence suggesting that myomectomy may be associated with better fertility outcomes than UAE, but more research is needed.

Therefore, in the absence of clear data to direct patient recommendations, the following approach is recommended:

1. Each patient's level of interest in pregnancy needs to be explored, particularly in relation to the patient's age, previous interventions, pregnancies, and interest in assisted-reproductive technologies. For most patients, this should be coupled with an assessment of current fertility status, including evaluation by a reproductive endocrinologist if appropriate.

2. For those patients without previous surgical interventions, with resectable leiomyomas, and with a reasonable likelihood of pregnancy based on other factors such as age, myomectomy may be preferred. However, given the weak evidence that favors myomectomy, patient preference for therapy should be respected, as long as the patient is well informed about our current knowledge of this issue.
3. For those with previous myomectomy, there are no reproductive outcomes from high-quality studies, and, given the difficulty of repeat surgery, embolization may be preferred.
4. The quality of the evidence to support the use of myomectomy to improve fertility is also very weak, without any data from randomized trials. Therefore, the uncertainty of outcomes from myomectomy should be included in the discussion with the patient.
5. For those who are poor surgical candidates because of comorbidity, body habitus, or extent or location of leiomyomas, uterine embolization is an acceptable choice for those seeking to become pregnant.

Appropriate Counseling for Patients Requiring Therapy for Symptomatic Leiomyomas and Adenomyosis

It is well recognized that the literature that can be used to guide discussions with patients considering therapies for these conditions is limited, particularly for acceptable alternatives to hysterectomy. Hysterectomy is effective, but has associated surgical risks and potential long-term negative outcomes (21,49,51,52), and is rejected by many patients as a therapeutic option. Many seek less invasive, uterine-sparing options and have the right to have reasonable alternatives presented to them. These options are supported by the American College of Obstetricians and Gynecologists 2008 Practice Bulletin on Alternatives to Hysterectomy in the Management of Uterine Leiomyomas (53).

UAE and Potential for Missed Diagnosis of Uterine Malignancy

One important risk to consider related to UAE is the potential that a uterine malignancy, such as leiomyosarcoma, might be present but not detected before the procedure. This risk has recently become a subject of public concern in reference to the use of power morcellation to assist laparoscopic surgery for uterine leiomyomas. This controversy has culminated in the release on April 17, 2014, of a United States Food and Drug Administration Safety Communication, "Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy," which discourages the use of the device (54). This communication is focused on the concern that power morcellation of individual tumors or the entire uterus will worsen the outcome in the case of a missed malignancy, as the morcellation is likely to spread the tumor throughout the pelvis. Although UAE is unlikely to spread malignant disease, uterine malignancy may be missed in patients undergoing the procedure, and this may result in a delay in diagnosis.

According to the Food and Drug Administration Communication (54), approximately one in 350 women who are undergoing hysterectomy or myomectomy for a presumed leiomyoma have an unsuspected uterine sarcoma. In a special report published in May 2014 (55), the American Congress of Obstetricians and Gynecologists estimated that the risk of missed malignancy was approximately one in 500 and noted that the risk varies with patient age and other patient-specific factors.

Interventional radiologists should inform patients about the risks associated with UAE, including the possibility of a missed diagnosis of cancer and a delay in definitive treatment. A realistic estimate of the frequency of missed malignancy based on the two aforementioned reports should be included in the information provided to patients.

Contraindications

The absolute contraindications to UAE are viable pregnancy; active (untreated) infection; and suspected uterine, cervical, or adnexal malignancy (unless the procedure is being performed for palliation or as an adjunct to surgery). The relative contraindications to UAE include coagulopathy, severe contrast medium allergy, and renal impairment, all of which can often be ameliorated. Some of these conditions also substantially increase the risk associated with surgery, and UAE may offer a safer option than surgery in some of these circumstances. Therefore, an individualized decision as to the safest choice of therapy should be reached in consultation with the patient and her gynecologist.

QUALITY IMPROVEMENT

Although 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.

Participation by the radiologist in patient follow-up is an integral part of UAE and will increase the success rate of the procedure. Close follow-up with monitoring and management of patients undergoing UAE is appropriate for the radiologist.

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 FIBROID was 14.4% at 3 years (4). Although this implies inadequate treatment of existing leiomyomata, a viable uterus may also give rise to new leiomyomata. 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 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 periprocedural 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 (Table 5). 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. 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 (56–66).

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 repeat intervention, 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 (67). Transient amenorrhea after UAE is usually limited to a few cycles (67) and is not considered a major complication. In patients who complete long-term follow-up, the authors of FIBROID reported an 11% rate of permanent amenorrhea at 6 months and 3 years after treatment (suggesting procedure-related amenorrhea) (4), but this has been associated with increasing age, occurring much more frequently in women older than the age of 45 years at the time of the procedure (4,68,69). Permanent

amenorrhea is classified as a major complication (permanent adverse sequelae), although some patients may not view it as such.

Although sexual dysfunction has been described following UAE (70), the few studies that specifically address this topic conclude that sexual function improves in the majority of patients (26,71,72). In a randomized trial comparing UAE versus hysterectomy, sexual functioning and body image scores improved in both groups but only significantly so after UAE (71).

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 (73); however, the radiation dose should be kept as low as possible to avoid injuries such as skin burns and ovarian dysfunction. Specific measures to decrease radiation dose include limiting the use of angiographic runs, and magnified views and oblique views to the extent possible. Aortography has been shown to contribute more than 20% of the total radiation dose for UAE while identifying substantial collateral ovarian flow in fewer than 1% of patients (74); 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 earlier. 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. All values given here are supported by the weight of literature evidence and panel consensus.

Table 4. Expected Outcomes of UAE for Leiomyomata

Outcome	Reported Rate (%)	Threshold (%)
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 a friend)	80–90	75

UAE = uterine artery embolization.

Table 5. Complications of UAE for Leiomyomata

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
DVT/pulmonary embolus	< 1	2
Nontarget embolization	< 1	< 1

DVT = deep vein thrombosis, UAE = uterine artery embolization.

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

Major Complications

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

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SIR DISCLAIMER

The clinical practice guidelines of the Society of Interventional Radiology (SIR) 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.