

Reporting Standards for Uterine Artery Embolization for the Treatment of Uterine Leiomyomata

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J Vasc Interv Radiol 2003; 14:S467-S476

Abbreviations: FSH = follicle stimulating hormone, PBAC = pictorial blood loss assessment chart, UAE = uterine artery embolization

UTERINE artery embolization (UAE) is an innovative treatment for symptomatic uterine leiomyomas, which are also called myomas or fibroids. Because the vascular supply of uterine leiomyoma is from the uterine arteries (1), embolization of these vessels leads to necrosis of these benign tumors. Several investigators have reported the infarction of leiomyoma alone, leaving the myometrium intact (2-4). Ravina et al (5) reported the first study in the English literature. Subsequent published studies have described a clinical success rate of 85%-89% (2,3,6-11). However, these studies have been case series and, to date, there have been no prospective comparative studies.

Clinical success has been measured by the degree of improvement or resolution of the primary symptoms of pain, bleeding, and bulk-related symptoms (2,3,5-11). Many published studies have evaluated patient outcome at follow-up office visits or with the use of symptom questionnaires. In most cases, these measures have not been validated. Objective evaluation for changes in uterine and leiomyoma

size has been largely based on ultrasonographic (US) findings, which are subject to substantial interobserver variability. Similar problems limit the quality of the data supporting other treatments for leiomyoma, such as hysterectomy and myomectomy. For these reasons and others, as the evaluation of this treatment proceeds, better measures of symptom and imaging outcome need to be developed.

This report is intended to serve as a guideline for investigators developing studies on UAE to improve the quality of the scientific data presented and published in the future. Study design, clinical definitions, imaging methods, and tools for measuring outcome will be reviewed with the goal of improving the validity of conclusions derived from clinical studies of UAE.

PRETREATMENT EVALUATION

Patient Selection

The patient populations in reported studies (2,3,5-11) represented those who expressed their desire for uterine preservation and/or avoidance of surgical procedures. Many of these patients had undergone failed medical and/or surgical therapy. Typical inclusion criteria for patients undergoing UAE have included abnormal menstrual bleeding, pain, and/or bulk symptoms specifically attributable to uterine leiomyomas. Bleeding associated with fibroids may be regular or irregular in interval. Some patients

have only heavy menstrual bleeding whereas others have heavy menstrual and intermenstrual bleeding. Typical exclusion criteria have included pregnancy; severe renal insufficiency (unless the patient is undergoing dialysis treatment); history of pelvic radiation; acute vasculitis; ovarian, uterine, endometrial, or cervical cancer; pelvic inflammatory disease or other pelvic infection; and endometritis. Because the effect on fertility has not been established, some studies have excluded patients who desired future fertility. Other exclusion criteria have included relative contraindications to arteriography, such as allergy to contrast material, and bleeding diathesis.

Recommendation for Reporting Standards

Any report should include a description of the population from which enrolled patients were recruited. Recruitment methods, including any patient or physician incentives, should be described. The inclusion criteria should be reported, including any definitions used by the investigators. Similarly, any exclusion criteria must be explicitly stated. The definitions for these criteria should be included if they may be subject to variable interpretation.

Baseline Data

Possible risk factors for the development and progression of leiomyoma include nulliparity and obesity, whereas oral contraceptive use, smoking, and

This article first appeared in J Vasc Interv Radiol 2001; 12:1011-1020.

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DOI: 10.1097/01.RVI.0000094620.61428.9c

pregnancy may be associated with a reduced risk of fibroid progression (12).

Goodwin et al (10) analyzed possible prognostic factors such as age, race, size, vascularity of the leiomyoma, and previous medical or surgical therapies. Only age and earlier myomectomy were significant prognosticators of the outcome. Further studies are needed to assess the validity of these prognostic factors.

Comorbid diseases may also affect the outcome of the procedure. Goodwin and colleagues (10) suggested that adenomyosis may "predispose" patients to clinical failure after the embolization procedure. Smith et al (13) reported a clinical failure after UAE in a patient with underlying adenomyosis. Other comorbid diseases that can affect clinical outcome include ovarian cysts, tubal inflammation, endometriosis, or diverticulosis. Patients with underlying diseases can have persistent pain after the procedure and therefore have a poor clinical outcome. Chronic salpingitis or endometritis may increase the chance of life-threatening infection. These comorbid conditions must be evaluated before UAE by performing a complete gynecologic history and physical examination as well as endometrial sampling, if indicated, and imaging studies.

Baseline data usually includes dominant leiomyoma size and position and an estimate of the number of leiomyoma. An actual count of leiomyoma may be very difficult, and therefore grouping of patients according to the number of fibroids is suggested. An outline of suggested criteria is given later in this article. Leiomyoma location within the uterus may correspond with outcome.

Some investigators have been concerned about the effect of uterine volume on the clinical outcome. However, Goodwin et al (10) failed to show any such correlation, and Bradley and Reidy (6) reported favorable outcomes in patients with uteri ranging from 14 to 28 weeks gestational size. Traditionally, these patients have been managed with hysterectomy (14). Further studies are needed to show whether UAE outcomes are affected by total uterine volume.

Imaging studies are used to assess leiomyoma size, position, and number. Most studies have been largely based on US findings, which can be

limited by substantial interobserver variability, particularly when estimating the size of large leiomyomas. Leiomyoma size and position and uterine size may be more accurately delineated with use of magnetic resonance (MR) imaging. MR imaging is also superior at delineating comorbid disease such as adenomyosis, which can be missed by US (15,16), or in diagnosing a malignant uterine mass. Imaoka et al (17) found MR imaging to have a sensitivity of 83%, a specificity of 92%, and an accuracy rate of 89% in distinguishing malignant from benign central uterine masses. However, the added cost of MR imaging may be prohibitive. Computed tomography (CT) is of little value in preprocedural assessment of leiomyoma.

Symptom severity and change have been assessed previously by simple questionnaires which are symptom-focused but have not been validated as reproducible and responsive to change. The SF-36 (18) and the SF-12 (19) are examples of standard quality-of-life questionnaires that may have applicability in UAE. The SF-12 has been reported as sensitive to change in health-related quality of life after UAE (19). Other examples are the Mental Health Index, General Health Index, and Activity Index used by Carlson et al (20) to assess the quality of life of women undergoing hysterectomy for various reasons. Broader, more reliable measures are needed (21,22). A disease-specific quality-of-life instrument for fibroids has been developed and validated (23). Pain severity can be quantitatively analyzed with use of a visual analog scale consisting of a 10-cm linear scale. Abnormal bleeding can be quantified with use of a method described by Higham et al (24) and later validated by Janssen et al (25). With use of the pictorial blood loss assessment chart (PBAC), consisting of diagrams representing lightly, moderately, and heavily soiled pads and tampons, the patient can record the number of pads and/or tampons used as well as the degree of saturation. A score can then be calculated by multiplying the number of "light," "moderate," and "heavy" pads and/or tampons by a corresponding fixed factor and summing the total. Alternatively, a questionnaire developed by Ruta et al (26) can be used. The Ruta scale is relatively easy to administer, whereas

the PBAC score requires a high degree of compliance on the part of the patients and investigators. Another more common quantitative measure of long-term blood loss is measurement of hemoglobin level.

Recommendations for Reporting of Baseline Data

As investigators design studies, they should carefully consider what baseline data are relevant to the intent of their protocol. Measures that will be reported as outcomes must be reported before and after therapy. For studies assessing the outcome from this therapy, the following baseline data should be collected and reported:

Demographic Data

- Age, race

Potentially Relevant Patient Data

- Patient weight, oral contraceptive, and tobacco use
- Age of menstrual onset (menarche)
- Pregnancy history and outcome
- Previous pathologic evaluation; ie, endometrial biopsy, hysteroscopy, and/or dilation and curettage
- Previous leiomyoma therapies
- Comorbid disease
- Follicle stimulating hormone (FSH) levels
- Hemoglobin levels
- Creatinine levels

Uterine and Fibroid Data

- Uterine size by physical examination
- Uterine and dominant fibroid size and/or volume
- Quantification of extent of fibroids: definitions
 - Single dominant (includes uteri with one primary symptomatic fibroid and no other potentially symptomatic fibroids greater than 2 cm)
 - Two to five fibroids, two or more of which are likely to contribute to the patient's symptoms
 - More than five fibroids, with five or more that are likely to contribute to the patients symptoms
 - Fibroid location within the uterus

The location of the dominant fibroid or codominant fibroids within

the uterus should be recorded when it can be determined. The following definitions are suggested:

- Pedunculated submucosal: a submucosal fibroid attached by a stalk narrower than 50% of the diameter of the fibroid.
- Broad-based submucosal or mixed intramural/submucosal: a broad-based fibroid that substantially distorts the endometrial lining of the uterus.
- Intramural: fibroid that is centered in the wall of the uterus with or without mild to moderate distortion of the endometrial or serosal surface.
- Transmural: fibroid centered in the myometrium but substantially distorting both the endometrial and serosal surfaces of the uterus.
- Subserosal: a fibroid centered in the outer myometrium with substantial distortion of the serosal surface of the uterus.
- Pedunculated subserosal: subserosal fibroid with its center outside the uterus attached to the uterus by a stalk narrower than 50% of the diameter of the fibroid.

Symptom Severity

Objective assessment of endpoints may be used. Examples include validated questionnaires that measure the following:

- Quality of life
- Pain severity
- Bulk symptoms
- Blood loss

TREATMENT DESCRIPTION

Technique

The results of UAE procedures reported from different institutions vary (2,3,5–11). This may be related to the level of experience (trainee or staff) of the physician performing the procedure. Various authors have reported the use of different procedures and/or techniques used for embolization. At some institutions, both uterine arteries are accessed via a single puncture site, whereas, at others, each uterine artery is catheterized via the contralateral common femoral artery approach. Other variations include the type and size of embolic material and the endpoint of embolization. The optimal

method for embolization is not yet defined and it is not known whether these technical variations are important. Therefore, reporting the details of the technique used is important.

Recommendation for Reporting Standards

The recommendations for reporting procedure technique are as follows:

1. Operator(s) training and specialty.
2. Number of cases performed at institution(s) before the start of the reported study.
3. Procedure duration: the length of the procedure from the time of the initial arterial puncture to the removal of the catheter should be reported.
4. Arterial access: the arterial access site(s) should be recorded for all cases; ie, whether unilateral or bilateral access was used.
5. Catheters: for technical papers, in which embolization methods constitute an important part of the purpose of the study, the details of the specific catheters, guide wires, and other angiographic supplies should be included. For example, the type(s) of catheters (size in French and shape) and whether a coaxial system and/or intra-vascular sheath are used should be reported.

Embolic Materials and Embolization Parameters

Katz et al (27) compared the effectiveness of gelatin sponge pledgets (Gelfoam; Upjohn, Kalamazoo, MI) versus polyvinyl alcohol for embolization. They concluded that the materials are equally effective, but only 17 patients were included in the entire study. Some investigators used polyvinyl alcohol alone (5,8), whereas others used gelatin sponge pledgets (10) or embolization coils (7) as adjunctive agents after polyvinyl alcohol embolization.

The definition of the endpoint of UAE has not been universally agreed upon, which affects the definition of a technically successful procedure and may also affect complications. Therefore, it is important for investigators to

define the endpoint used for their particular study. Endpoints that have been used in the past include:

1. Occlusion of the identifiable vessels supplying the fibroids, with preservation of as much of the normal uterine flow as otherwise possible;
2. Evidence of a “standing column of contrast” in the uterine artery and reflux toward the uterine artery origin or into the internal iliac artery; and
3. Cessation of flow in the ascending uterine artery with residual flow in the lower uterine segments supplying the normal myometrium.

Pharmacologic Adjuncts

Some authors have advocated or routinely used pharmacologic adjuncts before, during, or after the embolization procedure. These might be given intravenously, orally, or intraarterially and might include lidocaine, nitroglycerin, nifedipine, or other vasoactive substances.

Recommendation for Reporting Standards

The authors should report the characteristics of the embolic agents used, including the type (and manufacturer), size, and amount used. If more than one embolic agent is used, the sequence with which the agents are used should be indicated. The endpoint of embolization and success in achieving this endpoint for each treated artery should be described. Reasons for failing to satisfactorily reach the desired endpoint of embolization should be recorded (eg, failure to catheterize the uterine artery, arterial spasm, catheter dislodgment). Whether the cervicovaginal branch is visualized should be reported. If the branch is visualized, the method to protect blood flow in the branch should be reported. Reporting of use of any pharmacologic adjuncts including the dose, route of administration, and the timing of administration is recommended.

Anatomic Vascular Variation

Anatomic variations can contribute to technical failure (28,29). Hutchins et al (9) reported technical failures in the

following: one patient had one uterine artery branching off of the ovarian artery instead of the internal iliac artery and two patients had very tortuous uterine arteries. He also reported surgically ligated arteries that prevented catheterization.

Recommendation for Reporting Standards

The presence of congenitally variant or surgically altered (ligated) uterine arterial anatomy should be reported along with the influence that it had on the procedure. (Were accessory uterine arteries embolized? How were visible collaterals to/from the ovary handled?) Any ovarian arteriography or aortography performed should be reported along with the results.

Radiation Exposure

Radiation exposure occurring during UAE is a significant concern because many women who are candidates for the procedure are of childbearing age. One study suggests that the radiation dose associated with UAE is unlikely to cause patient injury or result in a measurable increase in the genetic risk to the patient's future children (30). None of the alternative therapies used to treat women with symptomatic leiomyomas involve exposure to radiation. In addition, data from a large number of patient procedures at different institutions has not yet been gathered.

Recommendation for Reporting Standards

The technical aspects of the imaging system used during the procedure should be reported whenever appropriate. This would include the type of angiographic equipment used to perform the procedures. The equipment manufacturer, model, and whether the unit has pulsed fluoroscopy are important technical details. The imaging method used, such as digital angiography or conventional (cut-film) angiography, should be reported. The fluoroscopy time and the number of angiographic images from all procedures should be recorded. Use of high-dose fluoroscopy should be reported.

Medications

Prophylactic antibiotics have been used widely in invasive procedures. No study has proven the value of prophylactic antibiotics in UAE, but prophylactic antibiotics may reduce the incidence of sepsis after percutaneous embolization and infarction of other solid abdominal organs (31).

Pain is a known sequela of any solid organ embolization, and analgesics have been used before, during, and after UAE procedures. Because UAE is intended to produce central necrosis of the leiomyoma, pain may indicate successful infarction and could be a positive predictor of clinical outcome. However, Roth et al (32) demonstrated no correlation between the severity of pain and outcome of the embolization procedure. A larger study may be able to show any significant correlation.

Recommendation for Reporting Standards

The protocol for preprocedural, intraprocedural, and postprocedural analgesia and for sedation and/or anesthesia (conscious sedation, regional anesthesia, or general anesthesia) should be reported. Any prophylactic antibiotic use should be noted. For inpatients, the length of hospitalization (in days) should be reported. For outpatients, the length of observation (in hours) should be reported.

POSTTREATMENT EVALUATION

Clinical success is difficult to quantify. Clinical success for an individual patient can be binary (eg, reduction in bleeding or pain if a threshold is set) or analog (eg, improvement in quality of life).

Clinical success for a group can be binary if there is a statistically significant improvement in outcome measures after treatment as compared to a control group. Alternatively, if no specific individual threshold is used, continuous data can be reported (ie, uterine size reduction, average change in pain scale or bleeding scale, etc). As noted previously, clinical outcome can be assessed by a variety of means, including measurement of the severity of the primary symptoms, change in the patient's health-related quality of

life, change in objective measures such as hemoglobin, Rute scale, or PBAC score, or by measuring patient satisfaction. With use of simple questionnaires, improvement of menorrhagia has been documented in as many as 88% of patients (2,3,5-11). These patients continued to have improvement of their symptoms even a year after the procedure (2,9-11). Improvement of pain and pressure symptoms has been reported in as many as 95% of patients (11).

Another measure of outcome is the effectiveness of UAE in avoiding other treatments for fibroids, as measured by subsequent medical therapies or surgery. As many as 10% of patients treated with UAE will subsequently undergo hysterectomy to treat UAE clinical failures, complications, comorbid diseases, or new disease (10). The usefulness of UAE compared to hysterectomy as therapy for leiomyomas will depend on the rate of subsequent hysterectomy, even if hysterectomy is performed for unrelated disease.

The effect UAE may have on subsequent fertility is unknown. All initial UAE series regarded desire to maintain fertility as a relative contraindication to UAE. Consequently, the first patients who underwent UAE usually did not desire to become pregnant. Despite this, normal pregnancies have been reported (6,9). The incidence of pregnancy among women who desire to become pregnant after undergoing UAE is not yet known.

Recommendation for Reporting Standards

For longitudinal studies, the follow-up intervals, mean follow-up duration, and range of follow-up duration should be reported. Typical follow-up intervals may be 1, 3, 6, 12, 18, and 24 months after the procedure. Both the number of patients evaluated at each interval and the number potentially available for follow-up at each interval should be reported. This will allow calculation of the follow-up rate at each interval. The protocol for follow-up at each of these intervals should be clearly defined. For studies that report success with use of binary definitions, success should be reported longitudinally with use of life tables (33).

If physical examination results are

Table 1
Definitions of Complications

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 h)
E. Permanent adverse sequelae
F. Death

to be reported, a number of parameters should be considered for inclusion. These might include change in uterine size by physical examination. If bulk/pressure signs such as varicose veins or edema of the legs were present on the previous examinations, follow-up findings should be reported.

Results of follow-up questionnaires regarding menstrual bleeding, pelvic pain, bulk symptoms, and overall quality of life should be reported. The method of questionnaire administration and an example of the text of the questionnaire and response choices should be included.

We recommend that any changes in blood loss should be reported according to the PBAC or Ruta scale at baseline and at least one follow-up interval. The PBAC should assess one menstrual period, or all periods in a single month if the patient has polymenorrhea (menstrual periods occurring more often than every 21 d). If neither the PBAC nor Ruta scale is used, a description of the method used to quantify blood loss should be included. If hemoglobin level is used, it should be reported at baseline and at an established follow-up interval.

In patients who develop amenorrhea, the results of any hormonal assays (eg, FSH level) or ovarian imaging should be reported. If the FSH level is found to be increased (>30 mIU/mL) (34), a second measurement should be conducted 2–4 weeks later to confirm ovarian failure (35). It should also be noted that women with ovarian failure may not be entirely amenorrheic and may menstruate and ovulate sporadically (36). It also may not be permanent.

Imaging data such as transabdominal or transvaginal US and/or MR im-

aging should be obtained at 12 weeks, 1 year, and 2 years. The same imaging techniques must be used before and after embolization. The absolute dimensions of the uterus and dominant leiomyoma should be measured and the approximate uterine and dominant leiomyoma volume and percent reduction of uterine and leiomyoma volume should be calculated for each imaging study. The formula for a prolate ellipse should be used ($\text{length} \times \text{depth} \times \text{width} \times 0.5233$).

The rate of subsequent hysterectomy and reasons for hysterectomy should be reported. The rate of repeat leiomyoma embolization or surgical uterine-sparing leiomyoma therapy should be reported.

For studies designed to assess fertility after UAE, the onset of menses after the procedure should be reported. Women who become pregnant should be followed closely, and complications and outcome of the pregnancy should be reported.

COMPLICATIONS

Discussion

Reported complications have been rare and can be divided into six general categories: complications of angiography, pelvic infection, ischemic phenomena, radiation injury, adverse drug reaction, and pulmonary embolus. Reported angiographic complications include groin hematoma, contrast reaction or nephrotoxicity, dissection of the uterine arteries during catheterization, and rupture of a vesical artery branch (9). Pelvic infection leading to hysterectomy has been described in one patient 5 weeks after embolization. Fatal sepsis has also been reported in one patient (37) and a

fatal complication occurred in another patient who died of massive pulmonary embolism 24 hours after the procedure (38). These complications are rare, but the risk is possibly increased with concurrent acute pelvic infection.

Postembolization syndrome occurs commonly after embolotherapy (39). Approximately 40% of women develop fever during the first week after UAE (9,10). This fever is often accompanied by pain, nausea, leukocytosis, and sometimes malaise. Distinguishing this syndrome from an acute infection poses a major concern among physicians. Postembolization syndrome is considered a complication when it results in prolonged hospitalization (beyond 48 h) or readmission or requires an unexpected increase in the level of care.

A very common postprocedural symptom is cramping or pelvic pain that can be severe enough to warrant admission to the hospital. A potential late complication is passage of tissue transvaginally (10,11). In some cases, this may require an emergent dilation and curettage and antibiotic therapy.

Transient and permanent amenorrhea after UAE has been reported. Amenorrhea is seen in 2%–5% of women after UAE, with permanent amenorrhea occurring in less than 2%, usually among patients of perimenopausal age (5,8,10,11). Amenorrhea may be caused by ovarian failure (suspected to be secondary to nontarget embolization of the ovaries) and/or endometrial atrophy. Measurement of FSH may be valuable in evaluating amenorrhea after UAE. As a woman ages or undergoes menopause, the ovarian follicles become resistant to stimulation by FSH, leading to a gradual increase in serum FSH level (34). Theoretically, if ovarian failure occurs, the FSH level should rise. A single measurement of >50 mIU/mL has been suggested as a reliable indicator of ovarian failure (34). Although there is considerable variability in the serum FSH level when measured randomly, measuring the FSH on day 3 of the menstrual cycle (basal FSH) will give the most accurate level to evaluate ovarian function (40). Measuring the FSH level in premenopausal women before the procedure will document their baseline ovarian function.

Sexual dysfunction possibly related to nontarget embolization of the cervi-

Table 2
Complications Master List (SIR)

Complication	Class
Abscess	Infectious/inflammatory
Angina/coronary ischemia	Cardiac
Idiosyncratic reaction	Medication-related
Allergic/anaphylactoid reaction	Contrast-related
Arterial occlusion/thrombosis, puncture site	Vascular
Arterial occlusion/thrombosis, remote from puncture site	Vascular
Arteriovenous fistula	Vascular
Congestive heart failure	Cardiac
Contamination of pleural cavity (urine, bile, malignancy, empyema, other)	Respiratory/pulmonary
Device malfunction with adverse effect	Device-related
Death related to procedure	Death
Death unrelated to procedure (30-d mortality)	Death
Embolization, arterial	Vascular
Fluid/electrolyte imbalance	General nonvascular
Hematoma bleed, remote site	Vascular
Hematoma bleed at needle, device path: nonvascular procedure	Vascular
Hematoma bleed, puncture site: vascular procedure	Vascular
Incorrect drug	Medication-related
Incorrect dosage	Medication-related
Intimal injury/dissection	Vascular
Ischemia/infarction of tissue/organ	Vascular
Incorrect site of administration	Medication-related
Local infection	Infectious/inflammatory
Liver failure	General nonvascular
Migration	Device-related
Myocardial infarction	Cardiac
Malposition	Device-related
Nausea/vomiting	General nonvascular
Other (cardiac)	Cardiac
Other (contrast related)	Contrast-related
Other (CNS complication)	Neurologic
Other dose-dependent complication	Contrast-related
Other (device related)	Device-related
Other (gastrointestinal)	General nonvascular
Other (general nonvascular)	General nonvascular
Other (hematologic)	General nonvascular
Other (infectious/inflammatory)	Infectious/inflammatory
Other (medication related)	Medication-related
Other (neurologic)	Neurologic
Other pleural complication	Respiratory/pulmonary
Other (respiratory/pulmonary)	Respiratory/pulmonary
Other (vascular)	Vascular
Pancreatitis	Infectious/inflammatory
Pulmonary embolism	Respiratory/pulmonary
Pulmonary embolism	Vascular
Peritonitis	Infectious/inflammatory
Hypotension	Cardiac
Hypoxia	Respiratory/pulmonary
Pulmonary edema	Respiratory/pulmonary
Peripheral nervous system complication	Neurologic
Pneumothorax	Respiratory/pulmonary
Pseudoaneurysm	Vascular
Respiratory arrest	Respiratory/pulmonary
Renal failure	Contrast-related
Arrhythmia	Cardiac
Septicemia/bacteremia	Infectious/inflammatory
Seizure	Neurologic
Septic shock	Infectious/inflammatory
Stroke	Neurologic
Tissue extravasation	Contrast-related
Transient ischemic attack	Neurologic
Unintended perforation of hollow viscus	General nonvascular
Vascular perforation or rupture	Vascular
Vagal reaction	Cardiac
Vasospasm	Vascular
Venous occlusion/thrombosis, puncture site	Vascular
Venous occlusion/thrombosis, remote from puncture site	Vascular

covaginal branch may occur in a small percentage of patients. Symptomatic nontarget embolization of nongynecologic organs (bowel, buttock, bladder, nerves, etc) must be reported if it occurs.

Other complications which are theoretically possible include radiation skin burns, pelvic vein thromboses, rhabdomyolysis with renal damage, intrauterine growth retardation, and uterine rupture during labor. If any of these occur, they should be reported.

Recommendation for Reporting Standards

All complications should be listed and graded according to previously defined SIR categories (Tables 1, 2). Complications and deaths occurring within 30 days of the procedure should be considered procedure-related. All complications and deaths occurring within the duration of the study should be recorded to assess long-term effects of UAE.

Symptoms of postembolization syndrome including pain and fever are expected outcomes. They should not be reported as complications, unless pain and/or fever results in prolonged hospitalization exceeding 48 hours or hospital readmission.

Postprocedural fevers qualifying as a complication should be documented along with a detailed history and physical examination and any laboratory evaluation such as white blood cell count. If known, the etiology of the fever (urinary tract infection, pelvic infection, postembolization syndrome, etc.) and the treatment should be reported. If patients are readmitted to the hospital, the reason for the readmission and the length of stay, in days, should be reported. The outcome of the hospitalization should also be reported.

Complications should be categorized as follows:

- Complications of angiography (dissection, renal failure, etc.)
- Pelvic infection
- Ischemic phenomenon
- Postembolization syndrome (requiring prolonged admission, readmission, or escalation of care)
- Ovarian failure
- Sexual dysfunction
- Fibroid tissue passage requiring intervention

- Nongynecologic embolization (bowel, buttock, bladder, nerves, etc.)
- Radiation injury
- Adverse drug reaction
- Pulmonary embolism
- Other

COMPARISON BETWEEN TREATMENT GROUPS

Currently, all reports are case series. There has been no study published comparing UAE to any other treatment modality. Comparative studies would be helpful. For example, a randomized controlled study comparing UAE to another uterusparing treatment such as myomectomy could be performed. This study would be beneficial to patients desiring retention of their uteri, and it would allow a simple, valid comparison of symptom change after treatment. Another possible study is one comparing UAE to hysterectomy. This study could provide data for comparative analyses of quality of life, improvement in symptomatology, and cost-effectiveness.

For a randomized study, all patients should be analyzed based on an intent-to-treat basis (ie, all comparisons should leave women in the group to which they were originally randomized even if they dropped out of the study or if treatment was not performed) and "per protocol" (ie, the analysis considers only patients receiving the intended treatment). Although crossover patients may be unavoidable, each subgroup must be clearly identified. Randomization should be performed with use of random number tables or computer programs and monitored by a third party not directly involved in the care of the patients. A power analysis should be performed before initiation of the study to assure that the study has sufficient power to detect differences that may be present.

Although randomized trials are ideal, valuable information can also be obtained from registries (41). Registries are most useful in identifying the indications and techniques that could be evaluated in subsequent randomized trials, evaluating technical aspects of the procedure, and documenting complications. They also give an indication of the effectiveness of an

intervention across a variety of practice types. One registry that is currently collecting data is the UAE Fibroid registry (42).

When possible, comparison groups could be stratified according to possible prognostic factors. For example, patients can be stratified according to age (premenopausal vs menopausal), race, comorbid diseases, leiomyoma size and location (subserosal, intramural, submucosal), vascularity, and previous medical and/or surgical therapies.

Recommendations for Reporting Standards

Patients should be analyzed based on intent to treat and per protocol. Studies should have a sufficient number of patients to have an 80% power to detect a desired difference with a 5% level of significance established by appropriate statistical tests.

COST

No cost-analysis study has been reported for UAE. Because charges at various institutions differ substantially and are not always well correlated with costs, it is recommended that costs be used for analysis (43).

Recommendation for Reporting Standards

Cost analysis is challenging and would best be performed as a separate study. Reporting standards for cost-analysis manuscripts are beyond the scope of this document.

CONCLUSION

UAE is a minimally invasive procedure for the treatment of uterine leiomyomas. Ideally, to make a valid clinical decision, a good case-controlled study or a randomized controlled study could be performed to accurately assess the safety, efficacy, and cost-effectiveness of UAE. Trials should be reproducible and should use validated and quantifiable instruments. Future studies should clearly define patient selection with use of predetermined inclusion and exclusion criteria. The ideal study is a prospective, randomized, controlled trial comparing UAE to standard surgical

Table 3
Recommendations for Reporting Standards

	Required	Highly Recommended	Recommended
Preprocedural Data			
Patient population			
Age, race	X		
Form of referral			X
Desire for fertility		X	
Gynecology/pregnancy history*	X		
Primary symptom necessitating treatment	X		
Risk factors†	X		
Comorbidities‡	X		
Study Design			
Inclusion criteria	X		
Exclusion criteria	X		
Primary endpoint(s)	X		
Secondary endpoint(s)	X		
Pictorial Bleeding Assessment Chart (PBAC) or Ruta scale		X	
Visual Pain Scale			X
SF-36 or equivalent		X	
Imaging	X		
MR imaging or US (see Text)	X		
Uterine size	X		
Dominant leiomyoma size	X		
Dominant leiomyoma location		X	
Leiomyoma number		X	
Prior medical therapy	X		
Prior surgical therapy	X		
Laboratory evaluation			
Creatinine			X
Hemoglobin§	X		
FSH			X
Papanicolaou Test	X		
Endometrial sampling			X
Procedure Data			
Operator training and specialty			X
Level of experience			X
Description of embolization procedure	X		
Catheters used			X
Embolic agent(s) used	X		
Pharmacologic adjuncts			X
Number of angiographic images			X
Anatomic variants	X		
Analgesic medications		X	
Antibiotics used		X	
Procedure time			X
Fluoroscopic time		X	
Complications	X		
Hospital days		X	
Postprocedural			
Clinical follow-up	X		
Postprocedural recovery time		X	
PBAC or Ruta scale			
Visual Pain Scale			X
SF-36 or equivalent			
1 year		X	
2 years		X	

* Gravida, parity, abortion, age of menses, regularity of cycle, menopausal status.

† Weight, oral contraceptives, tobacco.

‡ Endometriosis, adhesions, pelvic inflammatory disease, adenomyosis.

§ For patients presenting with abnormal bleeding.

|| For studies assessing fertility.

Table 3
Continued

	Required	Highly Recommended	Recommended
Laboratory evaluation			
Hemoglobin at 6 months [§]	X		
FSH at 6 months postprocedure			X
Imaging			
6 months	X		
1 year	X		
2 years	X		
Complications			
Angiography	X		
Pelvic infection	X		
Ischemic phenomenon	X		
Postembolization syndrome (see Text)	X		
Other (see text)	X		
Cost			X
Pregnancy		X	

* Gravida, parity, abortion, age of menses, regularity of cycle, menopausal status.

† Weight, oral contraceptives, tobacco.

‡ Endometriosis, adhesions, pelvic inflammatory disease, adenomyosis.

§ For patients presenting with abnormal bleeding.

|| For studies assessing fertility.

therapy; ie, myomectomy and/or hysterectomy. Possible endpoints to measure include improvement or resolution of primary symptoms such as menorrhagia, pelvic pain, and bulk-related symptoms. If possible, the overall quality of life should be assessed. Cost analysis is a major undertaking and may best be done as a separate study. The data should be analyzed based on the intent to treat and per protocol and the data should be analyzed with use of valid statistical methods.

The recommendations presented in this document should enable clinicians and researchers to design reproducible studies and to report data in a uniform and consistent manner. A summary of the reporting standards recommendations is shown in **Table 3**.

Acknowledgments: The Members of the Reporting Standards for Uterine Artery Embolization (UAE) Subcommittee are Alan H. DeCherney, MD, Francis L. Hutchins, MD, Lindsay S. Machan, MD, Bruce McLucas, MD, James B. Spies, MD, and Robert L. Worthington-Kirsch, MD. The Members of the UAE Task Force Standards Subcommittee are Nilesh H. Patel, MD, Robert T. Andrews, MD, Gerald A. Niedzwiecki, MD, Robert L. Worthington-Kirsch, MD, and Bruce R. Zwiebel, MD. The Members of the Society of Interventional Radiology Technology Assessment

Committee are David Sacks, MD, Chair, John Dean Barr, MD, Gary J. Becker, MD, Dana R. Burke, MD, Patricia E. Cole, PhD, MD, William B. Crenshaw, MD, Michael D. Dake, MD, Scott C. Goodwin, MD, Richard J. Gray, MD, Margaret E. Hansen, MD, Ziv Haskal, MD, Randall T. Higashida MD, John A. Kaufman, MD, Thomas B. Kinney, MD, Lindsay Machan, MD, Louis G. Martin, MD, Reed Ali Omary, MD, Nilesh H. Patel, MD, David A. Phillips, MD, Douglas C.B. Redd, MD, John H. Rundback, MD, and James E. Silberzweig, MD. Ex-Officio Positions: Curtis W. Bakal, MD, Curtis A. Lewis, MD, Kenneth S. Rholl, MD, and Terence Matalon, MD.

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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.