

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.

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