ACR Appropriateness Criteria® on Treatment of Uterine Leiomyomas

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Uterine leiomyomas (fibroids) are the most common tumors in women of reproductive age and a cause of significant morbidity in this patient population. Depending on the fibroid location, they can be the cause of a variety of symptoms, such as abnormal uterine bleeding, constipation, urinary frequency, and pain. Historically, hysterectomy has been the primary treatment option, and uterine fibroids remain the leading cause for hysterectomy in the United States. However, women who do not wish to undergo hysterectomy now have a variety of less invasive options available, including uterine artery embolization. This article discusses uterine artery embolization as well as some of the other treatment strategies for symptomatic uterine fibroids. In many situations, there may be no single best treatment option but several viable alternatives. Each option is discussed with consideration of outcomes, complications, and, when possible, cost-effectiveness. The recommendations in this article are the result of evidence-based consensus of the ACR Appropriateness Criteria. Expert Panel on Interventional Radiology.

Key Words: Appropriateness Criteria[®], uterine fibroids, uterine leiomyoma, uterine artery embolization, hysterectomy, myomectomy

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SUMMARY OF LITERATURE REVIEW

Uterine leiomyomas (also known as fibroids or myomas) are the most common tumors in women of reproductive age, affecting >66% of women by 50 years of age [1]. They are the leading cause of hysterectomy in the United States. Leiomyoma treatment is typically indicated to treat the symptoms of the fibroids, such as abnormal uterine bleeding, bulk-related symptoms, and pain.

Uterine Artery Embolization (UAE)

Appropriate patient selection and management are integral to successful outcomes with UAE. The following is a brief description of the procedure and patient management as detailed by the Society of Interventional Radiology Task Force on Uterine Artery Embolization [2].

Before UAE, all prospective patients should undergo a full gynecologic workup. Cross-sectional imaging, preferably ultrasound or MRI, is done to confirm the diagnosis of uterine leiomyomas and exclude other pelvic pathology. Viable pregnancy and active infection are two absolute contraindications for the procedure and must be excluded. The procedure is typically performed under conscious sedation using either a unilateral or bilateral

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common femoral artery approach, depending on operator preference. Both uterine arteries are selectively catheterized, when possible, with the catheter advanced distal to nontarget branches. Both uterine arteries are then embolized. The goal is the occlusion of all distal uterine artery branches feeding the leiomyomas. Particulate embolic agents are typically used to achieve a distal embolization. Afterward, the patient is observed and treated for postprocedural pain or nausea. The patient is followed closely for the first 24 to 48 hours after discharge for adequacy of pain and nausea control and to assess for potential complications. At 3 to 6 months after the procedure, the patient is reevaluated for treatment efficacy. Follow-up imaging may also be performed to determine fibroid volume reduction and to assess for incomplete fibroid infarction.

Outcomes. UAE was first reported in 1995 [3], and since that time, numerous reports have been published documenting clinical success rates of 81% to 100% [4-6]. Currently, registries remain the largest source of data for evaluating the efficacy of UAE. Results from the Ontario Uterine Fibroid Embolization Trial, a multicenter, prospective registry, showed median uterine and dominant fibroid volume reductions of 35% and 42%, respectively [7]. In addition, there was significant improvement for patients with menorrhagia (83%), dysmenorrhea (77%), and urinary frequency (86%) at 3 months after the procedure. One of the largest registries to date, the Fibroid Registry for Outcomes Data, comprised >3,000 women who underwent UAE at 72 sites. At 12 months, 95% of patients in whom there was follow-up reported symptomatic improvement and improved quality-of-life scores [8]. Recently, 36-month data were published for >1,200 patients enrolled in this registry [9]. These data showed continued statistically significant improvement in symptoms and quality of life on the basis of questionnaires. During the 3-year period, 14.4% of the patients underwent additional procedures (9.8% repeat UAE, 2.8% myomectomy, and 1.8% hysterectomy).

Complications. Overall, the reported complication rates for UAE remain low, with major complications occurring in $\leq 3\%$ of patients [5,10]. More commonly, up to 10% of patients may need to be readmitted for pain control. Amenorrhea can occur in up to 10% of patients after UAE. The risk for permanent amenorrhea seems to be age dependent. For women aged < 45 years, the risk is <2% to 3%, whereas for women aged > 45 years, it is up to 20% [11].

Durability. As with other uterine-sparing procedures, there is uncertainty about the durability of symptom relief with UAE. Trying to identify prospectively which patients will have better clinical results is difficult. Within the registry data, the two groups that showed better long-term outcomes were women presenting with abnormal uterine bleeding and women with smaller leiomyomas [9]. Nevertheless, in a small retrospective analysis, Scheurig et al [12] reported symptomatic improvement at 16 months in 5 of 6 patients with diffuse leiomyomatosis. In a retrospective analysis, Isonishi et al [13] found two preoperative factors to be predictive of success: hypervascularity of the nodules and multiplicity of nodules. Conversely, Firouznia et al [14] found no correlation between fibroid characteristics and outcome.

Overall, there is a 20% to 25% incidence of symptom recurrence at 5 to 7 years after UAE [15], though most women report continued high quality-of-life scores [16]. Lohle et al [17] reported continued symptom relief in 67 of 93 women (72%) at a median follow-up of 54 months. Of those patients with treatment failure, 11 (42%) underwent hysterectomies. In a separate study, 73% of patients maintained symptom control 5 years after the procedure. Despite the relatively high recurrence rate in long-term follow-up, repeat embolization has been shown to be effective for most of these patients [18], and UAE does not preclude other therapies when unsuccessful (see Variant 1).

Other Treatment Options

Hysterectomy. Hysterectomy is the most common treatment for symptomatic fibroids; approximately 150,000 to 200,000 hysterectomies are performed each year in the United States for fibroids, and it is considered the definitive therapy. The primary advantage is that by completely removing the uterus, there is little potential for fibroid recurrence. In addition, alternative causes of symptoms, such as adenomyosis, will also be effectively treated. Overall, this therapy is met with very high patient satisfaction scores, with up to 90% of patients reporting at least moderate satisfaction 2 years after hysterectomy for symptomatic fibroids [19]. However, many women who undergo hysterectomy later regret the loss of fertility or have concerns regarding their femininity [20].

To date, there have been 3 prospective, randomized trials comparing UAE to hysterectomy [19,21,22]. These studies have shown both treatments to have very high clinical success rates and very high rates of patient satisfaction. Within the study performed by the Randomized Trial of Embolization Versus Surgical Treatment for Fibroids investigators, women with symptomatic fibroids were randomly assigned to undergo either UAE or surgery in a ratio of 2:1 and followed for 1 year [21]. There were 95 women in the UAE group and 45 women in the surgical group, with most women in the surgical group undergoing hysterectomy. The UAE group had significantly shorter hospitalization stays and

Variant 1. 29-year-old woman with multiple submucosal and intramural fibroids presenting with menorrhagia and pelvic pain; most of the fibroids measure <4 cm in size, with two dominant fibroids measuring >6 cm; the patient states that she does not desire future pregnancies and is concerned about the loss of femininity with hysterectomy

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Treatment/Procedure	Rating	Comments	
Uterine artery embolization	8		
Hysterectomy	4	Should be considered. Patient preference important.	
Myomectomy	3	Suboptimal procedure due to multifocal fibroids.	
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.	
MR-guided high-frequency focused ultrasound ablation	3		
Endometrial ablation	2	Useful for menorrhagia but not pelvic pain. Young patient may change her mind about pregnancy.	
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.	
Note: Rating scale: 1, 2, and 3 = usually not ap	propriate; 4	1, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate.	

shorter recovery times before returning to work. At 12 months, the patients who underwent surgery had significantly better symptom scores, though there was no significant difference in quality-of-life scores.

The Embolization Versus Hysterectomy (EMMY) trial randomized 177 patients to undergo either UAE or hysterectomy and followed the women for 2 years. There was no significant difference in physical component summary scores beyond 6 weeks, and >90% of patients in each group were at least moderately satisfied with their procedures at 2-year follow-up. At 2-year follow-up, patients in the hysterectomy group had significantly higher satisfaction scores than patients in the UAE group.

As part of the EMMY trial, concerns over body image and sexuality were also evaluated between patients receiving hysterectomies and those receiving UAE [20]. At 2 years, there was no statistical difference in the sexuality or body image scores of the two groups (see Variant 2).

Myomectomy. Myomectomy is a surgical alternative that may be performed when uterine conservation is desired. As with other uterine-sparing procedures, there is a risk for myoma recurrence. Using either an abdominal or laparoscopic approach, the recurrence rate ranges from 23% to 33% [23-25]. In a large, multicenter study, laparoscopic myomectomy was associated with 2% major complication and 9% minor complication rates [26].

At least two studies have been performed directly comparing myomectomy to UAE. In one of the studies, there was a reduction in the procedural and recovery times, as well as fewer adverse events, with UAE; similar rates of clinical success were reported [27]. In a prospective, nonrandomized comparison, Siskin et al [28] demonstrated that UAE performed with spherical polyvinyl alcohol had a significantly greater sustained reduction in tumorrelated symptoms up to 24 months after intervention,

Variant 2. 45-year-old woman with multiple uterine fibroids resulting in a 20-week-sized uterus on physical examination and menorrhagia; the patient had a recent negative serum pregnancy test and has no desire for future fertility

Treatment/Procedure	Rating	Comments
Uterine artery embolization	8	Based on patient preference.
Hysterectomy	8	Based on patient preference.
Myomectomy	3	
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
MR-guided high-frequency focused ultrasound ablation	2	
Endometrial ablation	2	Controls bleeding, but patient remains at risk for bulk-related symptoms eventually.
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate.		

Treatment/Procedure	Rating	Comments
Myomectomy	8	May be most viable option if lesions are anatomically amenable to myomectomy.
Hysterectomy	7	
Uterine artery embolization	6	Less effective for bulk-related symptoms. Subserosal location may be relative contraindication.
MR-guided high-frequency focused ultrasound ablation	3	
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
Endometrial ablation	1	
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success

with fewer complications compared to myomectomy (see Variant 3).

High-Intensity Focused Ultrasound. MR-guided high-intensity focused ultrasound may be used to treat focal leiomyomas. It is a completely noninvasive treatment option, though each treatment may take several hours to complete. To date, there are very little data on the efficacy of this technology. It has been reported that myomas treated with high-intensity focused ultrasound have nearly 50% volume reduction at 1 year, but viable cells are present at biopsy in nearly 26% of specimens [29]. In a multicenter trial, Stewart et al [30] demonstrated significant reduction in fibroid-related symptoms in 70% of patients at 6 months and 51% of patients at 12 months.

Endometrial Ablation. Endometrial ablation is used for treating abnormal uterine bleeding from a variety of causes including symptomatic submucosal myomas. Because it ablates the uterine cavity, it should not be used in women desiring future pregnancy. There are also uterine cavity size limitations for most currently available devices, with most devices able to treat uterine cavities up to 10 cm in size [31]. In a study of 438 women treated with endometrial ablation for menorrhagia, there was >95% overall patient satisfaction [32]. Within this cohort, 143 patients were diagnosed preoperatively for uterine fibroids, 2 of whom went on to hysterectomy because of persistent symptoms associated with the uterine fibroids.

Laparoscopic Uterine Artery Occlusion (LUAO). There are limited published data about LUAO. In a small retrospective study, 9% of women developed myoma recurrence at a median follow-up of 23.6 months [33]. There are at least two studies comparing LUAO to UAE. In a small randomized controlled trial, LUAO achieved shorter hospital stays and reduced procedural pain compared to UAE, while achieving similar 3-month clinical success rates [34]. In a separate study, the degree of bleeding reduction was similar between the two procedures [35]. In this study, only 4% of patients treated with UAE continued to complain of symptoms, compared to 21% in the LUAO group (though this finding did not reach statistical significance).

Pharmaceutical Treatment. The least invasive treatment option remains medical therapy with either oral contraceptive medication or gonadotropin-releasing hormone agonists and antagonists. Oral contraceptives may manage bleeding symptoms effectively, especially in women with small fibroids. Gonadotropin-releasing hormone agonists have been shown in several studies not only to be effective against symptoms of bleeding but also to result in reduction in uterine volume and myoma volume, making them effective against bulk-related symptoms [36]. However, these agents have several drawbacks. First, once the agent is discontinued, the fibroids quickly return to their previous volumes, and the fibroid related symptoms typically recur. In addition, chronic use of gonadotropin-releasing hormone agonists results in trabecular bone loss. Therefore, these agents are typically used for temporary situations, such as to reduce uterine and myoma size before surgical therapy.

Other Considerations

Fertility. The issue of fertility after UAE remains an area of great controversy. The impact on future fertility and subsequent delivery remains uncertain. It has been shown that >60% of women who attempted to become pregnant after UAE had abnormal results on hysteroscopy [37]. However, the significance of these findings remains unknown. There are reports of uncomplicated pregnancies after UAE, but because of small sample sizes, the overall risk remains unclear [38,39]. In one study, 33

Variant 4. 36-year-old woman with menometrorrhagia; on MRI, she has 3 dominant leiomyomas, ranging in size from 6 to 8 cm and intramural in location; she states that she does not have current plans for future pregnancy but would like to have the option in the future

Treatment/Procedure	Rating	Comments
Uterine artery embolization	7	
Myomectomy	7	May be most viable option if lesions are anatomically amenable to myomectomy. Viable solution to preserve fertility.
MR-guided high-frequency focused ultrasound ablation	4	Early data favorable, but long-term data lacking.
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
Hysterectomy	2	
Endometrial ablation	1	
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Note: Rating scale: 1, 2, and 3 = usually not appropriate; 4, 5, and 6 = may be appropriate; 7, 8, and 9 = usually appropriate.		

of 56 women who went on to get pregnant after UAE had successful outcomes [40]. However, this and other studies have shown an increased incidence of delivery by cesarean section in the UAE patient population.

There have been several reports comparing the impact of UAE and myomectomy on fertility [41,42]. In a multicenter retrospective trial, Goldberg et al [41] found that women treated with fibroid embolization were at an increased risk for preterm delivery and breech presentation compared to women treated with myomectomy. In this same study, there was also an increased risk for postpartum hemorrhage and spontaneous abortion in the UAE group, but this difference did not reach statistical significance. Furthermore, in a prospective, randomized comparison, there was a statistically significant advantage for myomectomy in both the number of successful pregnancies and the number of early pregnancy losses [42]. When the risk for future pregnancy complications was studied in patients undergoing either UAE or LUAO, there was

also an increased risk for spontaneous abortion after UAE compared with LUAO [43] (see Variant 4).

Adenomyosis. Adenomyosis may be a cause of abnormal uterine bleeding with or without the presence of fibroids. UAE has shown early success in controlling the symptoms of bleeding with adenomyosis [44,45]. The long-term durability of this success is questionable, with recurrence rates at 2 years of approximately 40% to 50% [46,47] (see Variant 5).

Cost-Effectiveness. There have been several studies comparing the cost-effectiveness of UAE and hysterectomy. Two studies in Europe favored UAE as a more cost-effective treatment [48,49]. The investigators of the EMMY trial showed a 37% cost savings with UAE at 24 months after treatment [48]. The savings were seen in both the direct medical costs and the indirect costs from lost workdays. However, the medical cost advantage at 2

Variant 5. 41-year-old woman with menorrhagia; MRI reveals a single 3-cm intramural fibroid and diffuse adenomyosis

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Treatment/Procedure	Rating	Comments
Uterine artery embolization	7	Higher recurrence risk with adenomyosis.
Hysterectomy	7	May be best option, depending on patient preference.
Endometrial ablation	4	Data more favorable for treatment of fibroids as opposed to treatment of adenomyosis.
Myomectomy	3	
MR-guided high-frequency focused ultrasound ablation	3	
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Note: Rating scale: 1, 2, and 3 = usually not appropriate: 4, 5, and 6 = may be appropriate: 7, 8, and 9 = usually appropriate.		

years was partially offset by additional procedures incurred by the UAE group due to symptom recurrence in the follow-up period.

A second investigation, the Hysterectomy or Percutaneous Embolization for Uterine Leiomyomata study, used a probabilistic decision model to create a complex decision tree to compare the cost-effectiveness of the two procedures [49]. In this study, UAE was also shown to be more cost effective than hysterectomy up to 1 year after the procedure. Over time, however, UAE becomes more expensive than hysterectomy because of the cost of additional follow-up procedures. The authors concluded that "young women with less severe symptoms would benefit less from UAE than those who are older with more severe symptoms" [49].

In a study using Markov modeling, UAE proved to be more cost effective than either hysterectomy or myomectomy at 1 year [50]. However, at 5 years, hysterectomy proved to be the least expensive option.

SUMMARY

- Uterine artery embolization is effective in managing symptomatic uterine fibroids.
- Uterine artery embolization is more cost effective than hysterectomy in the short term, but hysterectomy becomes more cost-effective in the long term.
- Uterine artery embolization and myomectomy have similar clinical success and complication rates.
- Myomectomy may be superior to UAE in women planning future pregnancy.
- Uterine artery embolization is effective against symptoms related to adenomyosis, but the success may be limited by high recurrence rates.

Disclaimer: The ACR Committee on Appropriateness Criteria® and its expert panels have developed criteria for determining appropriate imaging examinations for the diagnosis and treatment of specified medical conditions. These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for the evaluation of a patient's condition are ranked. Other imaging studies necessary to evaluate other coexistent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the US Food and Drug Administration have not been considered in developing these criteria, but the study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

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