ACR Appropriateness Criteria® Radiologic Management of Uterine Leiomyomas

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Abstract

Uterine fibroids, also known as leiomyomas, are the most common benign tumor in women of reproductive age. When symptomatic, these patients can present with bleeding and/or bulk-related symptoms. Treatment options for symptomatic uterine leiomyomas include medical management, minimally invasive treatment such as uterine artery embolization, and surgical options, such as myomectomy. It is important to understand the role of these treatment options in various clinical scenarios so that appropriate consultation is performed. Furthermore, patients should be presented with the outcomes and complications of each of these treatment options. A summary of the data and clinical trials of the treatment options for symptomatic uterine leiomyomas is outlined in this article.

The American College of Radiology Appropriateness Criteria are evidence-based guidelines for specific clinical conditions that are reviewed annually by a multidisciplinary expert panel. The guideline development and revision include an extensive analysis of current medical literature from peer reviewed journals and the application of well-established methodologies (RAND/UCLA Appropriateness Method and Grading of Recommendations Assessment, Development, and Evaluation or GRADE) to rate the appropriateness of imaging and treatment procedures for specific clinical scenarios. In those instances where evidence is lacking or equivocal, expert opinion may supplement the available evidence to recommend imaging or treatment.

Key Words: Appropriateness Criteria, Appropriate Use Criteria, AUC, Endometrial ablation, Fibroids and fertility, MRgFUS, Myomectomy/hysterectomy, Uterine artery embolization, Uterine leiomyoma

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Disclaimer: The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). 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 evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent 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 FDA have not been considered in developing these criteria; however, 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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ACR Appropriateness Criteria® Radiologic Management of Uterine Leiomyomas. Variants 1 to 6 and Table 1.

Variant 1. Middle-aged woman with multiple uterine fibroids resulting in a 20-week-sized uterus on physical examination and menorrhagia. Bulk symptoms of urinary frequency and bloating are present. The patient has a recent negative serum pregnancy test and has no desire for future fertility.

Procedure	Appropriateness Category
Medical management	Usually Not Appropriate
MR-guided high-frequency focused ultrasound ablation	Usually Not Appropriate
Endometrial ablation	Usually Not Appropriate
Uterine artery embolization	Usually Appropriate
Laparoscopic uterine artery occlusion	Usually Not Appropriate
Myomectomy	Usually Not Appropriate
Hysterectomy	Usually Appropriate

Variant 2. Childbearing-age woman with multiple submucosal and intramural fibroids presents with menorrhagia and pelvic pain. Most of the fibroids measure <4 cm, with two dominant fibroids measuring >6 cm. Uterus is 12 cm on MRI. The patient states that she does not desire future pregnancies and is concerned about the loss of femininity with hysterectomy.

Procedure	Appropriateness Category
Medical management	Usually Not Appropriate
MR-guided high-frequency focused ultrasound ablation	Usually Not Appropriate
Endometrial ablation	Usually Not Appropriate
Uterine artery embolization	Usually Appropriate
Laparoscopic uterine artery occlusion	Usually Not Appropriate
Myomectomy	Usually Not Appropriate
Hysterectomy	May Be Appropriate

Variant 3. Childbearing age woman with menometrorrhagia. On MRI, she has three dominant leiomyomas, ranging in size from 6 to 8 cm and intramural in location. She states that she does not have plans for future pregnancy but would like to have the option in the future.

Procedure	Appropriateness Category
Medical management	Usually Not Appropriate
MR-guided high-frequency focused ultrasound ablation	May Be Appropriate
Endometrial ablation	Usually Not Appropriate
Uterine artery embolization	Usually Appropriate
Laparoscopic uterine artery occlusion	Usually Not Appropriate
Myomectomy	Usually Appropriate
Hysterectomy	Usually Not Appropriate

Variant 4. Middle-aged woman with menorrhagia. MRI reveals a single 3 cm intramural fibroid and diffuse adenomyosis.

Procedure	Appropriateness Category
Medical management	Usually Not Appropriate
MR-guided high-frequency focused ultrasound ablation	Usually Not Appropriate
Endometrial ablation	May Be Appropriate
Uterine artery embolization	Usually Appropriate
Laparoscopic uterine artery occlusion	Usually Not Appropriate
Myomectomy	Usually Not Appropriate
Hysterectomy	Usually Appropriate

Variant 5. Middle-aged woman with pelvic discomfort and 8 cm pedunculated subserosal fibroid on MRI.

Procedure	Appropriateness Category
Medical management	May Be Appropriate
MR-guided high-frequency focused ultrasound ablation	Usually Not Appropriate
Endometrial ablation	Usually Not Appropriate
Uterine artery embolization	Usually Appropriate
Laparoscopic uterine artery occlusion	Usually Not Appropriate
Myomectomy	Usually Appropriate
Hysterectomy	Usually Appropriate

Variant 6. Middle-aged woman with constipation. MRI reveals a 12 cm subserosal leiomyoma compressing the rectum.

Procedure	Appropriateness Category
Medical management	Usually Not Appropriate
MR-guided high-frequency focused ultrasound ablation	Usually Not Appropriate
Endometrial ablation	Usually Not Appropriate
Uterine artery embolization	Usually Appropriate
Laparoscopic uterine artery occlusion	Usually Not Appropriate
Myomectomy	Usually Appropriate
Hysterectomy	Usually Appropriate

Table 1. Appropriateness category names and definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

SUMMARY OF LITERATURE REVIEW

Introduction/Background

Uterine leiomyomas (also known as fibroids or myomas) are the most common tumor in women of reproductive age, affecting more than 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/or pain. Approximately 1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma [2].

DISCUSSION BY VARIANT

Variant 1: Middle-aged Woman With Multiple Uterine Fibroids Resulting in a 20-week-sized Uterus on Physical Examination and Menorrhagia. Bulk Symptoms of Urinary Frequency and Bloating are Present. The Patient has a Recent Negative Serum Pregnancy Test and has no Desire for Future Fertility

Variant 2: Childbearing-age Woman With Multiple Submucosal and Intramural Fibroids Presents With Menorrhagia and Pelvic Pain. Most of the Fibroids Measure <4 cm, With Two Dominant Fibroids Measuring >6 cm. Uterus is 12 cm on MRI. The Patient States that She does not Desire Future Pregnancies and is Concerned about the Loss of Femininity With Hysterectomy

Uterine Artery Embolization. Appropriate patient selection and management are integral to successful outcomes with uterine artery embolization (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 [3].

Before UAE, all prospective patients should undergo a full gynecologic workup, including a Pap smear every 3 years and/or an endometrial biopsy if a patient has menometrorrhagia. Cross-sectional imaging, preferably MRI, or ultrasound (US) is done to confirm the diagnosis of uterine leiomyomas and exclude other pelvic pathology. Viable pregnancy and active pelvic inflammatory disease 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 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(s). Particulate embolic agents are typically used to achieve distal embolization. Afterward, the patient is observed and treated for postprocedural pain and/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. Additionally, MRI after UAE is recommended to not only ensure adequate fibroid infarction but to exclude underlying leiomyosarcoma.

Outcomes. UAE for the treatment of uterine leiomyomas was first reported in 1995 [4], and since that time numerous reports have been published documenting clinical success rates of 81% to 100% [5-7]. 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 [8]. 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, included more than 3,000 women who underwent UAE at 72 sites. At 12 months, 95% of patients who were followed up reported symptomatic alleviation and improved quality-of-life scores [9]. For the more than 1,200 patients enrolled in this registry [10], 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 <3% of patients [6,11]. 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 appears to be age dependent. For women younger than 45 years of age, the risk is <2% to 3%, whereas for those >45 years of age, it is up to 20% [12].

Durability. As with other uterine-sparing procedures, there is uncertainty about the durability of symptom relief with UAE. Identifying 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 those with smaller leiomyomas [10]. Nevertheless, in a small retrospective analysis, Scheurig et al [13] reported symptomatic alleviation at 16 months in five of six patients with diffuse leiomyomatosis. In addition, a retrospective study showed no difference in outcomes or complications in patients with large fibroid volumes compared with published outcomes for other patients treated with UAE [14]. In a retrospective analysis, Isonishi et al [15] found two preoperative factors to be predictive of success: hypervascularity of the nodules and multiplicity of nodules. Conversely, Firouznia et al [16] found no correlation between fibroid characteristics and outcome.

Overall, there is 20% to 25% incidence of symptom recurrence at 5 to 7 years after UAE [17], though most women report continued high quality-of-life scores [18]. Lohle et al [19] reported continued symptom relief in 67 of 93 women (72%) at median follow-up of 54 months. Of those patients with treatment failure, 11 (42%) underwent hysterectomy. In a separate study, 73% of patients maintained symptom control 5 years after the procedure. Location of fibroids is of importance in adequately assessing appropriate patient selection. A retrospective study looked at women with cervical fibroids and found high treatment failure and reintervention rates in this particular group [20]. Similarly, greater than one submucosal fibroid has been associated with incomplete infarction, requiring repeat reintervention [21]. A study by Scheurig-Muenkler et al [22] also highlighted the impact of age on higher rates of treatment failure after UAE. In a study of 380 patients, a 23% treatment failure rate occurred at 10 years for UAE, which was significantly worse for patients <40 years of age. This age difference is likely due to the increased time available for recruitment of other collateral vessels (ie, the ovarian arteries) in these women. Despite the relatively high recurrence rate in long-term follow-up, repeat embolization has been shown to be effective for most of these patients [23], and UAE does not preclude other therapies when unsuccessful.

Endometrial Ablation. Endometrial ablation (EA) 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 [24]. In a study of 438 women treated with EA for menorrhagia, there was >95% overall patient satisfaction [25]. Within this cohort, 143 patients were diagnosed preoperatively with uterine fibroids, 2 of whom went on to hysterectomy because of persistent symptoms associated with the uterine fibroids. In a separate study, Glasser et al [26] found a 23% failure rate in treating patients with submucosal fibroids, compared with a failure rate of 4% in patients with normal uterine cavities.

Hysterectomy. Hysterectomy (total abdominal hysterectomy or laparoscopic) 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 [27]. However, many women who undergo hysterectomy later regret the loss of fertility or have concerns regarding their femininity and may undergo earlier onset of menopause [28]. Increased risk for ovarian failure is a possible consequence of premenopausal hysterectomy, even with ovarian preservation. In a prospective cohort study by Moorman et al [29], women who underwent hysterectomy with ovarian preservation still had a nearly twofold increased risk for ovarian failure.

To date, there have been multiple prospective, randomized trials comparing UAE with hysterectomy [27,30-32]. 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 at a ratio of 2:1 and followed for 1 year [30]. 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 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 trial randomized 177 patients to undergo either UAE or hysterectomy. 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. These improvements remained stable, with no significant difference between the two groups at 5-year follow-up [33].

As part of the Embolization Versus Hysterectomy trial, concerns over body image and sexuality were also evaluated between patients receiving hysterectomies and those receiving UAEs [34]. At 2 years, there was no statistical difference in the sexuality or body image scores of the 2 groups.

In a multicenter, nonrandomized prospective study, hysterectomy was compared with myomectomy and embolization for improving uterine fibroid-related symptoms and the effect on health-related quality of life [35]. This study, despite showing all three therapies as extremely effective in reducing fibroid-related symptoms, did demonstrate a significantly better health-related quality-of-life advantage for patients treated with hysterectomy.

Furthermore, a meta-analysis of the four randomized clinical trials including 515 patients comparing UAE with hysterectomy demonstrated significantly greater short-term benefits of UAE (shorter hospital stay, decreased blood loss) with similar long-term quality-of-life measurement but increased percentage of long-term reintervention [36].

Morcellation in minimally invasive hysterectomy can increase the risk for abdominopelvic recurrence and lower disease-free survival [37] in women who have underlying occult malignancy. Morcellation is not recommended because of risk for increasing stage of possible sarcoma.

Variant 3: Childbearing Age Woman With Menometrorrhagia. On MRI, she has Three Dominant Leiomyomas, Ranging in Size from 6 to 8 cm and Intramural in Location. She States that She does not have Plans for Future Pregnancy but Would Like to have the Option in the Future

Pharmaceutical Treatment. The least invasive treatment option remains medical therapy with either oral contraceptive medication or gonadotropin-releasing hormone (GnRH) agonists or antagonists. Oral contraceptives may manage bleeding symptoms effectively, especially in women with small fibroids. GnRH 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 [38]. However, these agents have several drawbacks. First, once the agent is discontinued, the fibroids quickly return to their previous volume, and the fibroid-related symptoms typically recur. In addition, chronic use of GnRH 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. Mifepristone, a partial progesterone agonist, has shown promising initial results; however, more long-term studies are needed [39].

Tranexamic acid is a nonhormonal agent that has been used previously for the treatment of dysfunctional uterine bleeding. Its role in abnormal menstrual bleeding attributed to uterine fibroids remains unclear. Its use may cause necrosis in fibroids and help reduce the menorrhagia associated with fibroids; however, adverse effects such as pelvic pain and fever may result [40].

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% [41-43]. In a large, multicenter study, laparoscopic myomectomy was associated with 2% major complication and 9% minor complication rates [44].

At least three studies have been performed directly comparing myomectomy with UAE. In one study, there was a reduction in the procedural and recovery times, as well as fewer adverse events, with UAE; however, similar rates of clinical success were reported [45]. Narayan et al [46] reported significantly higher symptomatic improvement scores for patients undergoing UAE compared with myomectomy, but there was no significant difference in patient satisfaction scores. The Prague Trial followed patients in both groups for a minimum of 12 months and found no difference in clinical outcomes. However, the UAE group had higher reintervention rates; 36% in the UAE group compared with 5% in the myomectomy group. Reintervention rates were higher in those patients who had fibroids >5 cm. In a prospective, nonrandomized comparison, Siskin et al [47] demonstrated that UAE performed with spherical polyvinyl alcohol had a significantly greater sustained reduction in tumor-related symptoms

up to 24 months after intervention, with fewer complications, compared with myomectomy.

Laparoscopic Uterine Artery Occlusion. There are limited published data about laparoscopic uterine artery occlusion (LUAO) as a stand-alone treatment for uterine leiomyomas. In a small retrospective study, 9% of women treated with LUAO developed myoma recurrence after a median follow-up period of 23.6 months [48]. There are several studies comparing LUAO with UAE. In a randomized evaluation of 20 patients, Ambat et al [49] found similar outcomes between the two procedures for menstrual blood loss, uterine volume, and volume of the dominant fibroid at 6 months, though menorrhagia symptoms did recur in 4 of 10 patients in the LUAO group. In another small randomized controlled trial, LUAO achieved shorter hospital stays and reduced procedural pain compared with UAE, while achieving similar 3-month clinical success rates [50]. In a separate study, the degree of bleeding reduction was similar between the two procedures [51]. In this study, only 4% of patients treated with UAE continued to report symptoms, compared with 21% in the LUAO group (though this finding did not reach statistical significance). After a median follow-up period of 48 months, there was clinical failure and symptom recurrence in 48% of patients treated with LUAO compared with 17% of patients treated with UAE [52]. In a prospective randomized study that included 96 patients, there was no significant difference in outcomes between the two treatment groups at 12 months [53].

In a meta-analysis of five trials involving 436 patients [54], LUAO was compared with UAE and myomectomy and found to be less effective in both clinical measures and patient satisfaction. In a prospective trial [55], UAE was more effective at causing complete ischemia of fibroids but was associated with greater risk for intrauterine necrosis (31% vs 3%).

High-Intensity Focused US. MR-guided high-intensity focused US (MRgFUS) is another uterine-sparing option to treat focal leiomyomas. It is noninvasive, though each treatment may take several hours to complete. Its use currently is restricted to patients with fewer than six leiomyomas or leiomyoma volume $< 900\ cm^3$ [56].

To date, there is little long-term information on the efficacy of this technology. It has been reported that myomas treated with MRgFUS have nearly 50% volume reduction at 1 year, but viable cells are present at biopsy in nearly 26% of specimens [57]. Funaki et al [58] reported a 24-month volume reduction of 40% with significant symptomatic improvement at 6 months that remained stable at 24-month follow-up. In a multicenter trial, Stewart et al [59] demonstrated significant reduction in fibroid-related symptoms in 70% of patients at 6 months and 51% of patients at 12 months.

Although a reasonable alternative for patients unable or unwilling to tolerate sedation or anesthesia [58], long-term data and viability results are still lacking. Froeling et al [60] compared MRgFUS with UAE and found significantly higher reintervention rates (67% vs 12%) and lower quality of life.

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 more than 60% of women who attempted to become pregnant after UAE had abnormal hysteroscopies [61], particularly [62] with higher incidence of intrauterine necrosis (43%). 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 [63,64]. In one study, 33 of 56 women who went on to get pregnant after UAE had successful outcomes [65]. Another study [66] demonstrated a 50% success rate (22 of 44) for patients desiring pregnancy, without any significant increase in complication rate during their pregnancies.

There have been several studies comparing the impact of UAE and myomectomy on fertility [67,68]. In a multicenter retrospective trial, Goldberg et al [67] found that women treated with fibroid embolization were at an increased risk for preterm delivery and breech presentation compared with 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 the only 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 [68]. However, it should be noted that in this study, myomectomy was allowed in 26% of patients who underwent UAE with fibroids >5 cm persisting at 6 months. Therefore, one-fourth of the UAE cohort underwent both UAE and myomectomy procedures. The UAE group also had a higher failure rate (11%) than in most studies. Additionally, the myomectomy group underwent either laparoscopic or open procedures, which calls into question the generalizability of results. 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 [69].

A meta-analysis [70] looked at the outcomes of all reported pregnancies in women (n = 227) who had undergone UAE compared with control subjects from a variety of studies that looked at reproductive outcomes. The significant complications from UAE in these women included an increase in miscarriage (35%), an increase in cesarean sections (66%), and an increase in postpartum hemorrhage (13.9%).

Studies to date demonstrate that UAE should not be considered the first-line choice in women seeking pregnancy, and myomectomy should be offered as the first therapeutic choice. UAE can still be considered in this subgroup of women in certain situations, such as those who are poor surgical candidates, those who have fibroids that are not surgically resectable, and those who have had repeated myomectomies. Although myomectomy is seen as the standard option, there is no robust evidence, and studies need to be performed to investigate whether UAE is superior, inferior, or equal to myomectomy. There is very limited evidence that myomectomy may be superior to UAE in women planning future pregnancy, and higher quality research is needed [5]. In younger women who have a reasonable chance of future fertility, myomectomy may be a better option, although patient preference for UAE should be respected, as long as patients are well-informed on the current evidence. The ongoing UK FEMME trial is a randomized prospective clinical trial that hopes to answer this question.

Another treatment option for patients who are candidates is MRgFUS. However, to date, there is little information regarding the issue of fertility after MRgFUS. In a review of registry data, 54 pregnancies were reported in 51 women [71]. Of these, 41% resulted in live births and 28% in spontaneous abortions. Of those who delivered, there was a 93% term delivery rate, with only one preterm birth (36 weeks). Forty-three percent of pregnancies had an associated complication, but no pattern of complications was seen.

Variant 4: Middle-aged Woman With Menorrhagia. MRI Reveals a Single 3-cm Intramural Fibroid and Diffuse Adenomyosis

Comorbidities. 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 [72,73]. The long-term durability of this success is questionable, with recurrence rates at 2 years of approximately 40% to 50% [74,75]. In a recent review by Popovic et al [76], long-term symptomatic relief (median follow-up, 27.9 months) in patients with pure adenomyosis or adenomyosis with coexistent leiomyomas ranged from 65% to 82%. Additionally, more recent retrospective studies (median follow-up ranging from 24 to 65 months) have reported symptomatic control in 73% to 88% [77-79]. A prospective study by Kim et al [80] demonstrated significant symptom relief with 83% showing complete adenomyosis necrosis. Therefore, with most recent data showing durability in symptom control and no current therapy demonstrating superiority over the other, UAE for adenomyosis should be considered for patients presenting with symptomatic adenomyosis or concomitant adenomyosis and uterine leiomyomata.

Endometriosis is another cause of abnormal bleeding and can coexist with fibroids. Surgical methods for fibroids and endometriosis can be performed simultaneously, and surgery may be more appropriate in this population [81].

Variant 5: Middle-aged Woman With Pelvic Discomfort and 8 cm Pedunculated Subserosal Fibroid on MRI

Variant 6: Middle-aged Woman With Constipation. MRI Reveals a 12 cm Subserosal Leiomyoma Compressing the Rectum

Both UAE and surgical options (myomectomy and hysterectomy) are viable alternatives in the control of bulk-related symptoms secondary to fibroids. Regarding pedunculated subserosal fibroids, in the past, a case report described postembolization necrosis of the fibroid stalk (defined as a stalk diameter <50% of the greatest diameter of the fibroid) with the fibroid detaching into the pelvis, resulting in hysterectomy. On the basis of this report, the presence of pedunculated subserosal fibroids was considered a potential contraindication to UAE [82]. However, more recent studies have addressed these concerns. At least two studies found no instances of fibroid detachment with good clinical outcome and no complications after UAE [83,84]. Although one study found pedunculated subserosal fibroids to be associated with higher treatment failure rates (which may have been attributable to the small sample size of the failure group and methodology used to determine UAE success [85]), the previous safety concerns have not been validated in larger studies, and symptom improvement is similar among patients without pedunculated leiomyomas [83,84,86].

SUMMARY OF RECOMMENDATIONS

- Variant 1: Uterine artery embolization or hysterectomy is appropriate.
- Variant 2: Uterine artery embolization is appropriate.
- Variant 3: Myomectomy or uterine artery embolization is appropriate.
- Variant 4: Uterine artery embolization or hysterectomy is appropriate.
- Variant 5: Uterine artery embolization, myomectomy, or hysterectomy is appropriate.
- Variant 6: Uterine artery embolization, myomectomy, or hysterectomy is appropriate.

SUMMARY OF EVIDENCE

Of the 87 references cited in the *ACR Appropriateness Criteria® Radiologic Management of Uterine Leiomyomas* document, 75 are categorized as therapeutic references including 6 well-designed studies, 38 good-quality studies, and 12 quality studies that may have design limitations. Additionally, 8 references are categorized as diagnostic references. There are 27 references that may not be useful as primary evidence. There are 4 references that are meta-analysis studies.

The 87 references cited in the *ACR Appropriateness Criteria® Radiologic Management of Uterine Leiomyomas* document were published from 1991 to 2016.

Although there are references that report on studies with design limitations, 44 well-designed or good-quality studies provide good evidence.

SUPPORTING DOCUMENTS

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

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