UTERINE FIBROIDS

Select from these topics
- Uterine Fibroids
- Anatomy
- Standard Treatments
- Uterine Fibroid Embolization
- UFE Clinical Outcomes

Prepared in Collaboration with:
Gary Siskin, M.D.
Albany Medical Center
Uterine fibroids are also called myomas or leiomyomas (LIE-O-MY-O-MA)

What are uterine fibroids?
• Non-cancerous tumors of muscle tissue that can enlarge or distort the uterus.

What causes fibroids:
• Exact cause is unclear, but evidence suggests that genetics and hormones (primarily estrogen or progesterone) are most closely linked to fibroids.

Why do fibroids matter?
• Depending on size and location, fibroids can require treatment due to abnormal uterine bleeding, pain and pressure symptoms.
Fibroids affect approximately **25 million** women in the United States.

About **6 million** women in the U.S. are symptomatic enough to see a doctor.

**20% to 40%** of women aged 35+ have uterine fibroids of significant size.

African-American women are **3-5x more likely** to have fibroids than white, Asian or Hispanic women.
Most fibroids are asymptomatic (50% to 80%), but the three most common symptoms for women with significant fibroids are listed below:

- Heavy, prolonged menstrual periods, which can be associated with clots.  
  **Note:** Abnormal uterine bleeding can have many causes, including – but not limited to – fibroids.

- Increased menstrual cramping
- Pelvic pain or discomfort
- Pain in the back, sides or legs
- Pain during sexual intercourse

- Frequent urination due to pressure on bladder
- Constipation due to pressure on bowel
- Bloating or distension of the abdomen

The presence and severity of these symptoms will depend on the location, size and number of fibroids.
How are fibroids found?
- Fibroids are typically diagnosed by pelvic exam and then confirmed by ultrasound or MRI.

Image of a fibroid
(shown here as a round mass in the top left), as seen on a transvaginal ultrasound.

What tests are required?
- All pre-procedure evaluations require a blood count and pregnancy test. Endometrial evaluation by hysteroscopy may also be required if there is a very irregular pattern of uterine bleeding.
Uterine Fibroids

Abnormalities & Fibroid Size

Other abnormalities found on imaging can potentially change the treatment plan:
- Adenomyosis
- Adnexal masses
- Endometrial abnormalities

Usually more than one fibroid, ranging widely in size from pea to melon.

Fibroids may enlarge the uterus to the size of a 6-7 month pregnancy.

When should an IR consider treatment?
When patients have fibroids and significant symptoms or rapid fibroid growth.
UTERINE FIBROIDS

Select from these topics
- Uterine Fibroids
  - Overview
  - Incidence & Prevalence
  - Common Symptoms
  - Testing & Imaging
  - Abnormalities & Size
  - Types of Fibroids
  - Penduculated Fibroids
  - Referral & Treatment Algorithm
- Anatomy
- Standard Treatments
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Uterine Fibroids | Types of Fibroids

**Subserosal Fibroids**
- 55% of all fibroids
- Subserosal fibroids are located in the outer wall of the uterus
- Typically cause ‘bulk’ or pressure symptoms

**Intramural Fibroids**
- 40% of all fibroids
- Intramural fibroids are found in the muscular layers of the uterine wall
- Can cause abnormal bleeding or pressure symptoms

**Submucosal Fibroids**
- 5% of all fibroids
- Submucosal fibroids are found on the inside of the uterus, next to the uterine cavity.
- Often cause abnormal bleeding.

Images provided by Gary Siskin, MD
Pedunculated Fibroids
Small percentage of all fibroids

- Fibroids can also be connected to the uterus by a stalk or be attached to nearby organs, such as the bladder, bowel or nearby uterine ligaments.

Pedunculated Subserosal

Pedunculated Submucosal

Images provided by Gary Siskin, MD
Treatment for uterine fibroids has an unclear pathway, but the four factors below are very often considered as part of the physician-patient discussion about treatment.

Treatment Pathways for Women with Fibroids:

- **Pathway #1**
  - Most Common
  - Gynecologist
  - Pathway #2
  - Looking for Alternatives to Hysterectomy
  - Interventional Radiologist
  - UFE

- **Hysterectomy**
- **Myomectomy**

GYN and IR may refer to one another, although it is less common.
UTERINE FIBROIDS

Select from these topics
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  - Uterine Anatomy
  - Uterine Anatomy with Fibroids
  - How to Read the MRI
  - Uterine Artery Anatomy
  - Tortuous Uterine Artery
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Uterine Fibroids

Uterine Anatomy

![Diagram of Uterus, Cervix, Fallopian tubes, Ovary, and Vagina]
Small percentage of fibroids are pedunculated

- Submucosal: 5%
- Subserosal: 55%
- Intramural: 45%
UTERINE FIBROIDS

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Uterine Fibroids | How to Read the MRI

Normal Uterus on MRI

Uterus with Fibroids

Images provided by Gary Siskin, MD
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Uterine Fibroids | How to Read the MRI

Uterus with Adenomyosis

Junctional Zone is dark and thickened with subendometrial cysts, which is consistent with adenomyosis.

Endometrial Cavity (No Fibroids Present)

Uterus with Fibroids

Fibroids

Bladder

Endometrial Cavity

Images provided by Gary Siskin, MD
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Uterine Fibroid Embolization (UFE) | Uterine Artery Anatomy

Ideal catheter position for embolization (distal to cervicovaginal branch)

Image provided by Gary Siskin, MD
Much more tortuous uterine artery, compared with the previous image.

In these tortuous uterine arteries, it is very difficult to identify the cervicovaginal branch of the uterine artery. Moving the microcatheter into a more-distal position can increase the risk of spasm or vessel dissection, and so a more proximal position is preferred.

However, even in tortuous anatomy, the ideal catheter position for embolization is beyond the descending portion of the uterine artery and into the transverse segment.
About half of the 600,000 hysterectomies performed in the U.S. each year are due to fibroids.

What is a hysterectomy?
- Hysterectomy is the surgical removal of the uterus. The ovaries may or may not be removed. This is a permanent solution to uterine fibroids.
UTERINE FIBROIDS

Select from these topics
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  - Hysterectomy
  - Myomectomy
- Uterine Fibroid Embolization
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Uterine Fibroids  Hysterectomy

Clinical Outcomes & Complications

- Permanent solution to fibroids
- Standard of care treatment for uterine fibroids

Risks / Complications include:
- Excessive bleeding
- Bladder or bowel injury
- Early-onset menopause, even if the ovaries are not removed
- Blood clots
- Infection

Recovery after Hysterectomy

- Hospital stay of 3-4 days
- Home recovery of 4-6 weeks
  - No lifting
  - No sexual activity
- No chance of future fertility

[Full list of References]
**Uterine Fibroids**

**Myomectomy**

**What is a myomectomy?**
- Myomectomy is the surgical removal of uterine fibroids through the abdomen with small incisions, or through the vagina with hysteroscopy.

**What to Know?**
- Preferred option for patients who desire future fertility
- Fibroids can grow back after myomectomy; recurrence rate is higher for women with multiple fibroids

**Recovery after Myomectomy**
- Abdominal myomectomy recovery time is about 4-6 weeks
- Hysteroscopic myomectomy recovery time is less than 1 week
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  - Embozene Microspheres
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UFE | History & Development

Estimated UFE Procedures in 2015
About 12% of Global Peripheral Embolization Procedures (20% in U.S.)

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>First results of UFE reported by French gynecologist Jacques Ravina</td>
</tr>
<tr>
<td>1999</td>
<td>Popularity of UFE begins to increase with small-center trials</td>
</tr>
<tr>
<td>2000-2003</td>
<td>Large-scale clinical trials (up to 650 patients) show marked improvement in symptoms &amp; fibroid volume</td>
</tr>
<tr>
<td>1997</td>
<td>First U.S. experience in UFE reported by IR Scott Goodwin &amp; GYN Bruce McLucas at UCLA</td>
</tr>
<tr>
<td>2008</td>
<td>American Congress of Obstetricians &amp; Gynecologists (ACOG) declares UFE is 'safe and effective' based on short- and long-term outcomes</td>
</tr>
</tbody>
</table>

United States 28,000  Global 95,000

About 12% of Global Peripheral Embolization Procedures (20% in U.S.)


[Full list of References]
**Uterine Fibroid Embolization (UFE) | Overview**

**What is UFE?**
- An IR procedure to access and infarct uterine fibroids through the vascular anatomy while preserving the uterus.

**What to Know?**
- Involves the bilateral embolization of uterine arteries with embolic particles, which block blood flow to the fibroids and cause fibroids to shrink.
- Preservation of uterine artery flow is desired so that the normal myometrium, which is not involved with fibroids, continues to receive blood flow.
- Procedure is performed under conscious sedation and not general anesthesia.
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Uterine Fibroid Embolization (UFE) | How to Perform UFE

[Diagram of Uterine Fibroid Embolization]

[Boston Scientific]

[Full list of References]
Uterine Fibroid Embolization (UFE) | IR Technique

Common Techniques

- **Unilateral common femoral artery access**: Used by most centers.

- **Bilateral femoral access**: Shown to reduce fluoroscopy time, procedure time, and puncture site pain with no increase in complications.¹

- **Catheter placement distal to cervicovaginal branch**: Preserving this vessel may reduce the incidence of sexual dysfunction after UFE.

- **Completion Angiography**: Abdominal aortogram performed after embolization to see if uterine arteries have been embolized and to determine if there are any other blood vessels supplying the fibroids.

- **Unilateral ovarian artery embolization**: Can be performed to ensure successful infarction, but bilateral OAE should be avoided. Risk of permanent amenorrhea associated with OAE is similar to reported incidence after UAE.²

UTERINE FIBROIDS

Uterine Fibroid Embolization (UFE) | Embolic Agents

Best outcomes:
- Polyvinyl alcohol (PVA flakes, shown in top syringe below), tris-acryl gelatin microspheres (middle syringe), and hydrogel microspheres (calibrated spheres, shown in lower syringe) have been found to be most effective for UFE with the best clinical outcomes and highest infarction rates.¹,²

Most common sizes:
- **PVA**: 355–500μm and 500–710μm
- **Tris-acryl (Embosphere)**: 500–700μm and 700–900μm
- **Hydrogel (Embozene)**: 700μm and 900μm

Angiographic endpoints:
- **PVA**: Stasis of flow is desired.
- **Tris-acryl (Embosphere)**: Slow forward flow in the main uterine artery.
- **Hydrogel (Embozene)**: Slow forward flow in the main uterine artery.


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Uterine Fibroid Embolization (UFE) | Embozene Microspheres

- Received U.S. indication to treat uterine fibroids in 2014
- Multiple studies in Europe have shown safety and effectiveness

![Stampfl Study, CVIR 2010](image1)

<table>
<thead>
<tr>
<th>Clinical Results</th>
<th>Embozene™ Microspheres</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>121</td>
</tr>
<tr>
<td>Volume Reduction of Dominant Fibroid at 1-Year Follow-Up</td>
<td>91%</td>
</tr>
<tr>
<td>Improved Hypermenorrhea at 2-Year Follow-Up</td>
<td>94%</td>
</tr>
<tr>
<td>Improved Dysmenorrhea at 2-Year Follow-Up</td>
<td>95%</td>
</tr>
<tr>
<td>Patient Satisfaction (-3 = Not satisfied at all to +3 = Perfect satisfaction)</td>
<td>+2.7</td>
</tr>
</tbody>
</table>

![Smeets Study, JVIR 2010](image2)

<table>
<thead>
<tr>
<th>Clinical Results</th>
<th>Embozene™ Microspheres</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>86</td>
</tr>
<tr>
<td>Patients with 100% complete infarction in dominant fibroid</td>
<td>69</td>
</tr>
<tr>
<td>Patients with greater than 90% infarction in dominant fibroid</td>
<td>81</td>
</tr>
<tr>
<td>Health-Related Quality of Life Score (HRQOL) Before UAE with Embozene (Asymptomatic population score = 86)</td>
<td>53</td>
</tr>
<tr>
<td>HRQOL at 1-Year Follow-Up after UAE with Embozene</td>
<td>90</td>
</tr>
</tbody>
</table>

Uterine Fibroid Embolization (UFE) | Microspheres vs. PVA*

**Clinical Results**

<table>
<thead>
<tr>
<th>Embosphere® Microspheres</th>
<th>Contour™ PVA Particles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Bleeding Score</td>
<td>3.2</td>
</tr>
<tr>
<td>Fibroid-Specific Symptom Score</td>
<td>21.3</td>
</tr>
<tr>
<td>Quality of Life Total Score</td>
<td>81.9</td>
</tr>
<tr>
<td>Presence of Uninfarcted Fibroid (%)</td>
<td>23%</td>
</tr>
<tr>
<td>Presence of Complications</td>
<td>20%</td>
</tr>
</tbody>
</table>

**Procedural Results**

<table>
<thead>
<tr>
<th>Embosphere® Microspheres</th>
<th>Contour™ PVA Particles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolic Volume/Patient (ml)</td>
<td>9.4</td>
</tr>
<tr>
<td>Frequency of Catheter Occlusion (%)</td>
<td>4%</td>
</tr>
</tbody>
</table>

**Conclusions:**

1. “Tris-acryl gelatin microspheres and PVA particles are similarly effective for UAE in terms of fibroid infarction and symptom improvement, with no outcome advantage with either material.”

2. “No single difference was detected in any outcome variable. Pain, medication use, and other symptoms were the same.”

Uterine Fibroid Embolization (UFE) | Recovery after UFE

What Patients Feel After UFE

- Recovery after UFE is the most difficult part for patients.
- All patients feel some level of Post-Embolization Syndrome (PES)
- Symptoms of PES include:
  - Pelvic pain or cramping
  - Nausea, vomiting
  - Fever
  - Malaise

How Symptoms are Treated

- Medications, either IV or orally, required for all patients for nausea and pain control
- Overnight observation is standard due to the need for IV pain control
- Most pain improves within 5 days
- Most patients able to return to normal activity within 7 – 10 days after UFE
- **Outpatient UFE is possible and done in many areas of the United States**

Uterine Fibroid Embolization (UFE) | Complications & Risks

**Immediately after the procedure:**
- Angiographic complications
- Allergic drug reactions
- DVT / PE

**Delayed, or sometime after the procedure:**
- Infection
- Uterine ischemia
- Uteroenteric fistula (an abnormal connection between ureter and gastrointestinal tract)
- Pedunculated fibroids are thought to potentially increase the risk of UFE, due to fibroids detaching into uterine cavity
- Permanent impact on ovarian function, such as amenorrhea (lack of menstrual function)

Premature amenorrhea appears to be age-related, with most occurrences happening in patients age 45 or older.

<table>
<thead>
<tr>
<th>Age at UFE</th>
<th>Amenorrhea after 3 years</th>
<th>Amenorrhea after 6 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 40</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>40 – 44</td>
<td>1.4%</td>
<td>11.2%</td>
</tr>
<tr>
<td>&gt; 44</td>
<td>19.7%</td>
<td>40.4%</td>
</tr>
</tbody>
</table>


[Full list of References]
**Uterine Fibroid Embolization (UFE) | Complications & Risks**

**Transcervical Fibroid Expulsion:**
- Most women tolerate this well, with 49% requiring no operative intervention.
- However, some need hysteroscopy (8%), transvaginal myomectomy (27%) or hysterectomy (16%).


Images provided by Gary Siskin, MD.
Most patients with symptomatic fibroids are candidates for UFE...

But how do you find out if UFE is the right procedure?

5 Key Questions for Patient Selection

1. Does patient have fibroids?
2. Does patient have bothersome symptoms?
3. Can symptoms be attributed to fibroids?
4. Is it likely that UFE will help or harm the patient?
5. Does the patient want to have children in the future?
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UFE | Comparison of Standard Treatments & UFE

For UFE
- Shorter hospitalization and faster return to work than standard treatments
- Higher patient satisfaction than standard treatments
- More people recommend UFE to friend than hysterectomy or myomectomy
- Lower rate of adverse events compared with standard interventional treatments

Against UFE
- Myomectomy has better reproductive outcomes than UFE
- Minor complication rate is higher with UFE (includes pain control issues)
- Most studies of UFE vs. hysterectomy show at least one symptom that improves better with hysterectomy than with UFE (no overall differences in symptomatic improvement)
Uterine Fibroid Embolization (UFE) | Opinions by GYN Community*

“More research is required before UFE can be recommended as a routine treatment option.”

2000 ACOG Practice Bulletin

“UFE, when performed by experienced physicians in appropriate candidates, appears to provide short-term reduction in the uterine and fibroid size, as well as short-term improvement in menstrual bleeding and other fibroid-related symptoms.”

2004 ACOG Practice Bulletin

“Based on long- and short-term outcomes, UFE is a safe and effective option for appropriately selected women who wish to retain their uteri (Level A).”

2008 ACOG Practice Bulletin

Level A means the recommendation is based on good and consistent scientific evidence.

Women who want UFE should still have a thorough evaluation with their OB-GYN to facilitate optimal collaboration with IR and to ensure the chosen therapy is appropriate.

*Obstet Gynecol 2008; 112:387-400.
UTERINE FIBROIDS

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  - Fibroid Volume Reduction
  - Fibroid Infarction
  - Fertility

UFE Clinical Outcomes | Symptom Improvement¹,²

Key Takeaway: UFE is safe and makes patients feel better.

Fibroid Registry
- Multi-center study sponsored by SIR to assess UFE outcomes
- 3,160 patients enrolled (2,666 evaluated at 6 and 12 months)

<table>
<thead>
<tr>
<th></th>
<th>Initial Score Before UFE</th>
<th>6 Months after UFE</th>
<th>12 Months after UFE</th>
<th>Normal Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom Control Score</td>
<td>59.8</td>
<td>19.8</td>
<td>19.2</td>
<td>22.5</td>
</tr>
<tr>
<td>Health-Related QOL Score</td>
<td>47.3</td>
<td>85.0</td>
<td>86.7</td>
<td>86.4</td>
</tr>
</tbody>
</table>

Other Studies Show Short- and Long-Term Symptom Improvement
- Early data: Improvement in menorrhagia (79 – 98%) and bulk symptoms (64 – 98%)
- 6-year data: Symptomatic recurrence rate of 17%, with most of these patients requiring re-intervention¹
- 8-year data: Additional treatment rate of 25% and hysterectomy rate of 22%²


[Full list of References]
UTERINE FIBROIDS

UFE Clinical Outcomes | Fibroid Volume Reduction

**Key Takeaway:** UFE decreases volume of uterus and fibroids.

Note: Patients are more likely to be dissatisfied if their fibroid volumes are reduced less than 30% and more likely to be satisfied if volume reduction is greater than 56%.

<table>
<thead>
<tr>
<th>Study Author (Year)</th>
<th>Number of Patients</th>
<th>Symptom Improvement %</th>
<th>Fibroid Volume Reduction %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ravina (2000)</td>
<td>286</td>
<td>93%</td>
<td>60% (fibroids)</td>
</tr>
<tr>
<td>Spies (2001)</td>
<td>200</td>
<td>90%</td>
<td>N/A</td>
</tr>
<tr>
<td>McLucas (2001)</td>
<td>167</td>
<td>86%</td>
<td>52% (uterus) 37% (fibroids)</td>
</tr>
<tr>
<td>Walker (2002)</td>
<td>400</td>
<td>84%</td>
<td>53% (uterus) 64% (fibroids)</td>
</tr>
<tr>
<td>Pron (2003)</td>
<td>550</td>
<td>83%</td>
<td>35% (uterus) 42% (fibroids)</td>
</tr>
</tbody>
</table>

*Spies, et al. Obstet Gynecol 2005; 106(5 Pt 1):933*
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  - Fertility

**UFE Clinical Outcomes**

**Fibroid Infarction**

**Key Takeaway:** More infarction is correlated with better outcomes.

Women with fibroid infarction rates above 90% on MRI after UFE show significantly better symptom control and fewer reinterventions than patients with a lower infarction rate.¹

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[Full list of References]
**UTERINE FIBROIDS**

**UFE Clinical Outcomes**  |  Fibroid Infarction

**Key Takeaway:** More infarction is correlated with better outcomes.

<table>
<thead>
<tr>
<th>% Fibroid Infarction</th>
<th>Patients</th>
<th>Rate of Symptom Control</th>
<th>Rate of Additional GYN Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>142</td>
<td>93%</td>
<td>3%</td>
</tr>
<tr>
<td>90 – 99%</td>
<td>74</td>
<td>71%</td>
<td>15%</td>
</tr>
<tr>
<td>&lt;90%</td>
<td>5</td>
<td>60%</td>
<td>20%</td>
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**Uterine Fibroids**

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  - Fertility

---

**UFE Clinical Outcomes | Fertility**

**Key Takeaway:** It is possible after UFE, but myomectomy is still best option.

---

**What to Know**

- Papers published that support and refute the idea of fertility after UFE.
- Limited clinical studies have been published to support that patients can conceive and deliver healthy babies after UFE.
- Amenorrhea, due to ovarian failure, and/or endometrial atrophy are possible after UFE.
- Miscarriages, abnormal placentation, preterm delivery and malpresentation have all been reported in pregnancies after UFE (We do not yet know if these are related to UFE or other possibilities).

---

**Recommendations**

- Myomectomy is considered the best option for patients who desire fertility after treatment for fibroids.
- Prospective study, UFE vs. Myomectomy, showed superior reproductive outcomes for myomectomy in first two years after treatment.
- 121 patients with intramural fibroids > 4cm
- UFE should not be the first consideration for patients seeking fertility.
- Important to inform patients of all risks and benefits of all fibroid treatment options.

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[Full list of References]
IMPORTANT INFORMATION

These materials are intended to describe common clinical considerations and procedural steps for the on-label use of referenced technologies as well as current standards of care for certain conditions. Of course, patients and their medical circumstances vary, so the clinical considerations and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding patient care depend on the physician’s professional judgment in light of all available information for the case at hand.

BSC does not promote or encourage the use of its devices outside their approved labeling.

The presenter’s [or author’s] experience with BSC products may not be interpreted or relied upon to support clinical claims about BSC devices or product comparison claims regarding BSC and competitive devices. The experiences of other users may vary.

REFERENCES