

UTERINE FIBROIDS



Select from these topics

- ☐ Uterine Fibroids
- ☐ Anatomy
- ☐ Standard Treatments
- ☐ Uterine Fibroid Embolization
- ☐ UFE Clinical Outcomes

Prepared in Collaboration with:
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Albany Medical Center



UTERINE FIBROIDS



Select from these topics

- Uterine Fibroids
 - Overview
 - Incidence & Prevalence
 - Common Symptoms
 - Testing & Imaging
 - Abnormalities & Size
 - Types of Fibroids
 - Pedunculated Fibroids
 - Referral & Treatment Algorithm
- Anatomy
- Standard Treatments
- Uterine Fibroid Embolization
- UFE Clinical Outcomes

Uterine Fibroids | Overview

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.



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Uterine Fibroids | Incidence & Prevalence of Fibroids

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



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Uterine Fibroids | Common Symptoms of Fibroids

Most fibroids are asymptomatic (50% to 80%), but the three most common symptoms for women with significant fibroids are listed below:

Abnormal Uterine Bleeding

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

Pain Symptoms

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

Pressure Symptoms

- 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



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Uterine Fibroids | Testing & Imaging for Fibroids

How are fibroids found?

- Fibroids are typically diagnosed by pelvic exam and then confirmed by ultrasound or MRI.

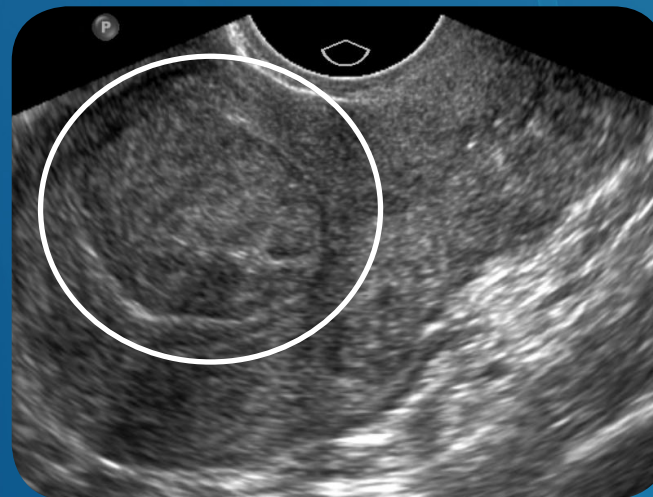


Image of a fibroid

(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.



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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



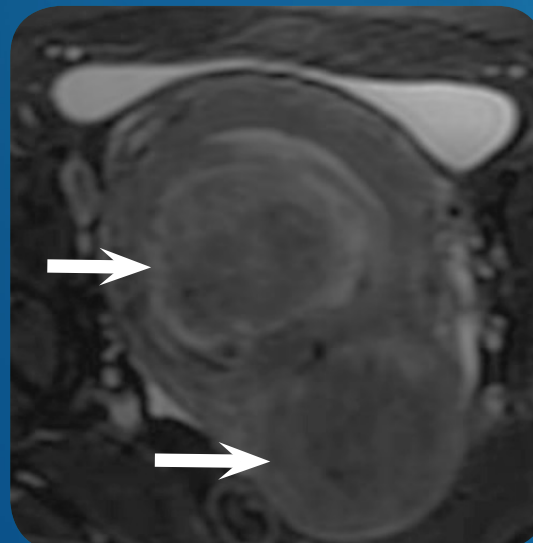
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Uterine Fibroids | Types of Fibroids

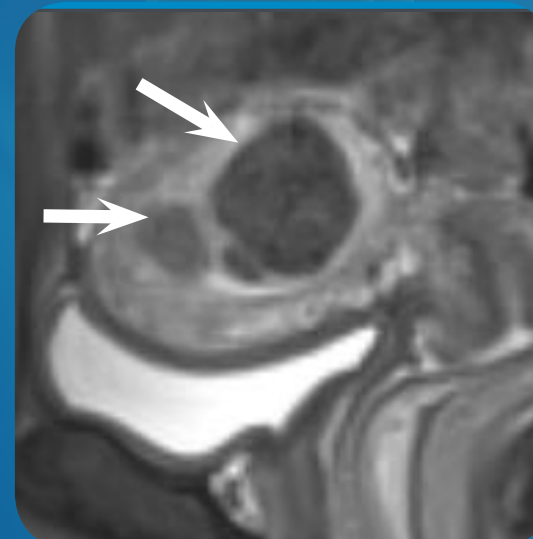
Subserosal Fibroids
55% of all fibroids

- Subserosal fibroids are located in the outer wall of the uterus
- Typically cause 'bulk' or pressure symptoms



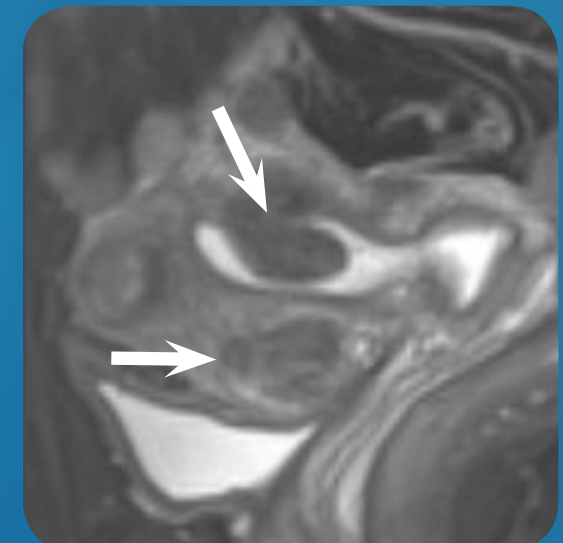
Intramural Fibroids
40% of all fibroids

- 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.



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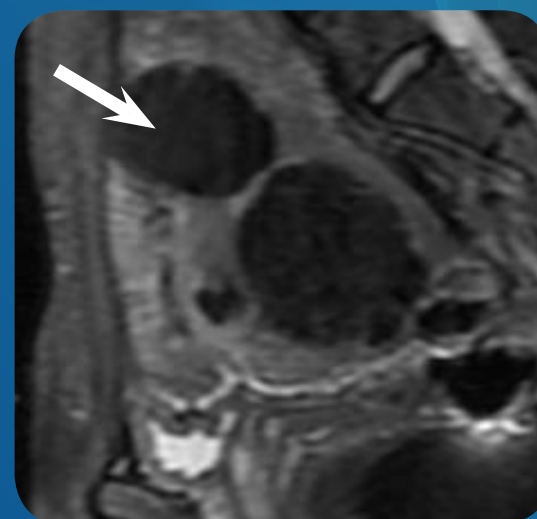
Uterine Fibroids | Penduculated Fibroids

Pedunculated Fibroids

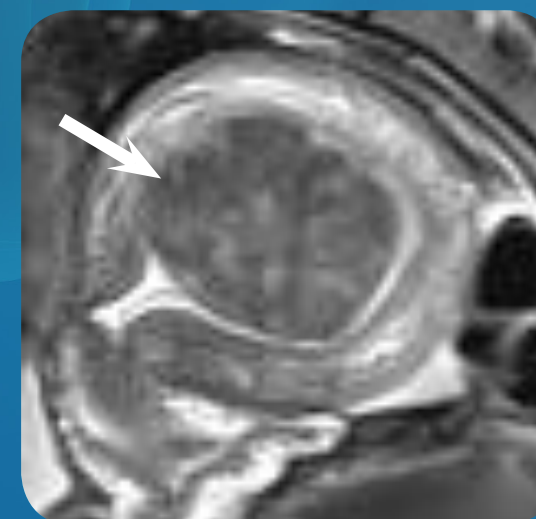
Small percentage of all fibroids

- 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



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Uterine Fibroids | Referral & Treatment Algorithm

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.

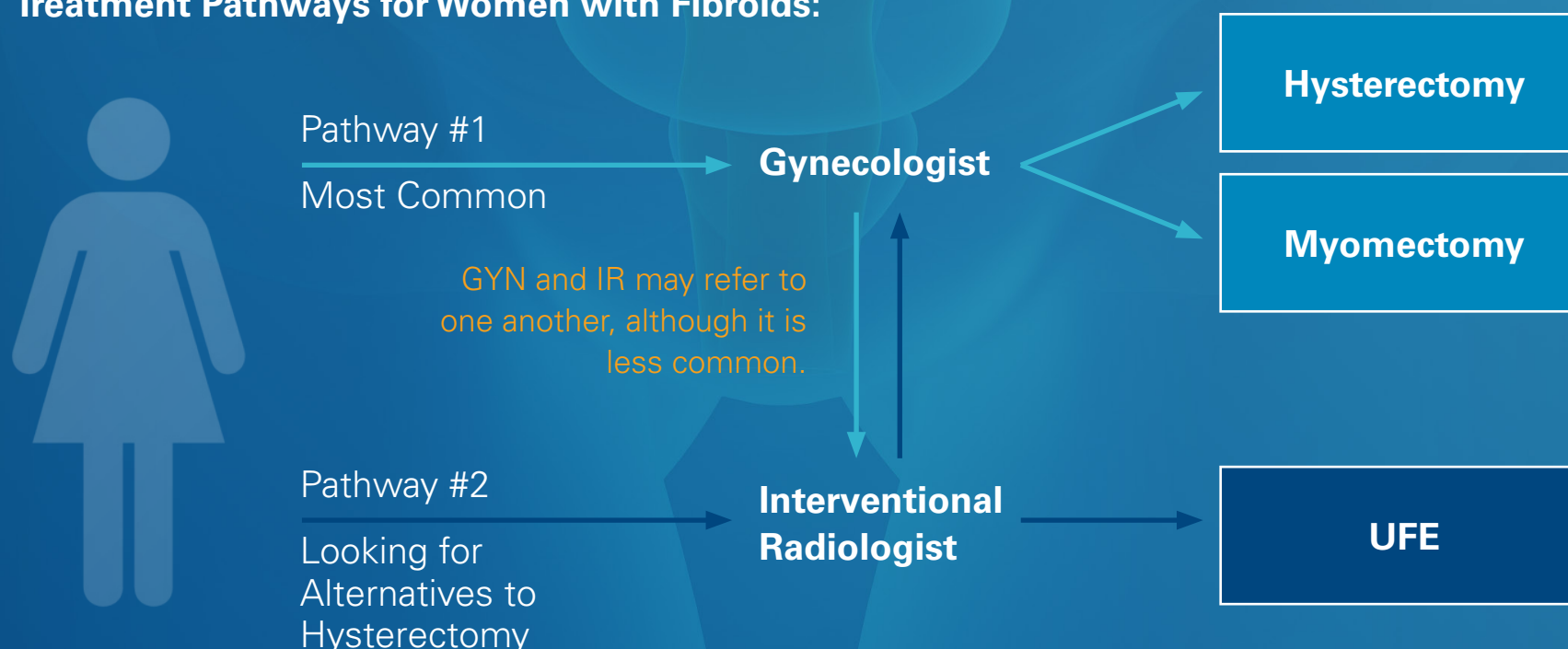
Size of Fibroids

Symptoms

Desire for Fertility

Patient Preference

Treatment Pathways for Women with Fibroids:



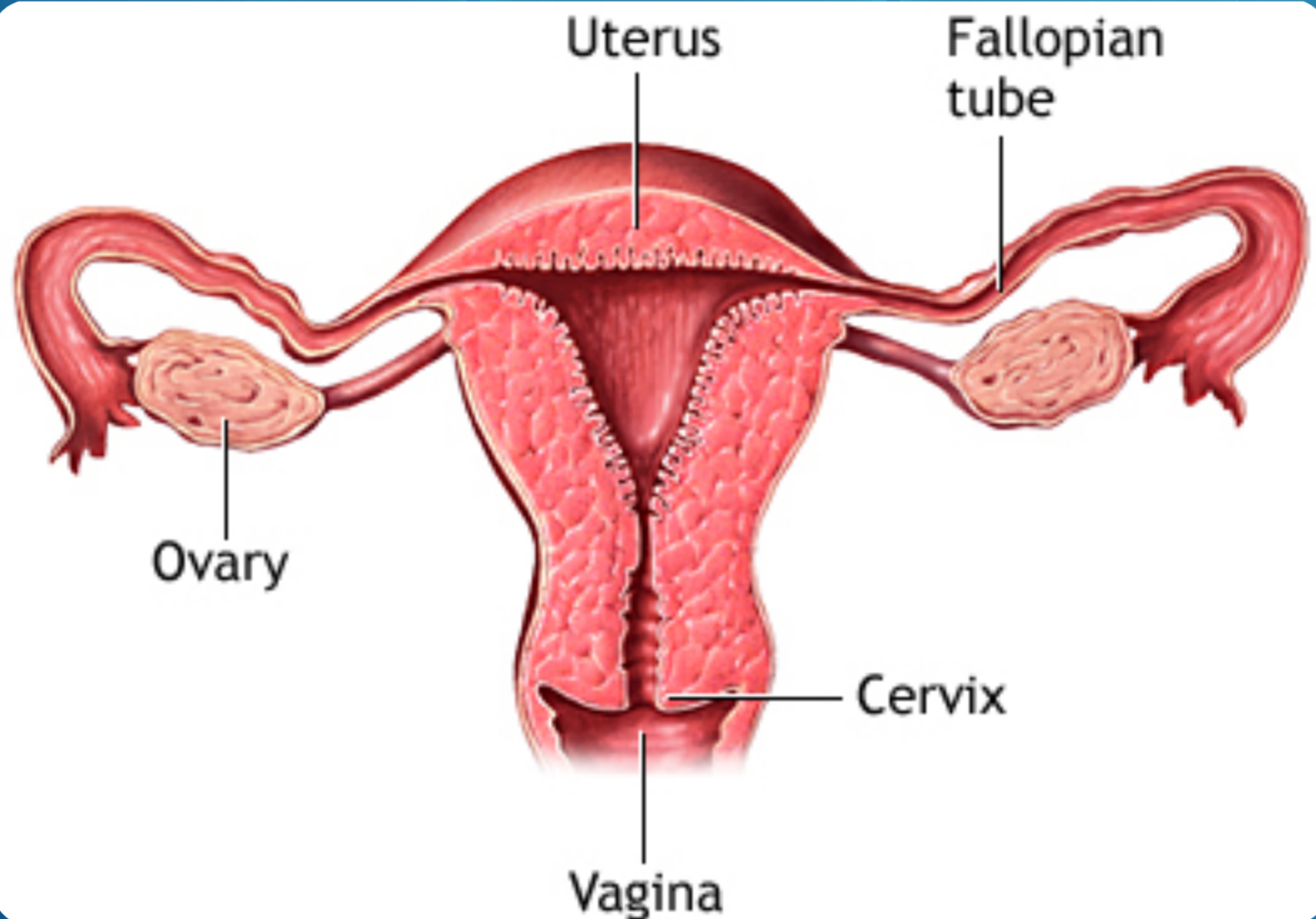
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 - ☐ Uterine Anatomy with Fibroids
 - ☐ How to Read the MRI
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Uterine Fibroids | Uterine Anatomy



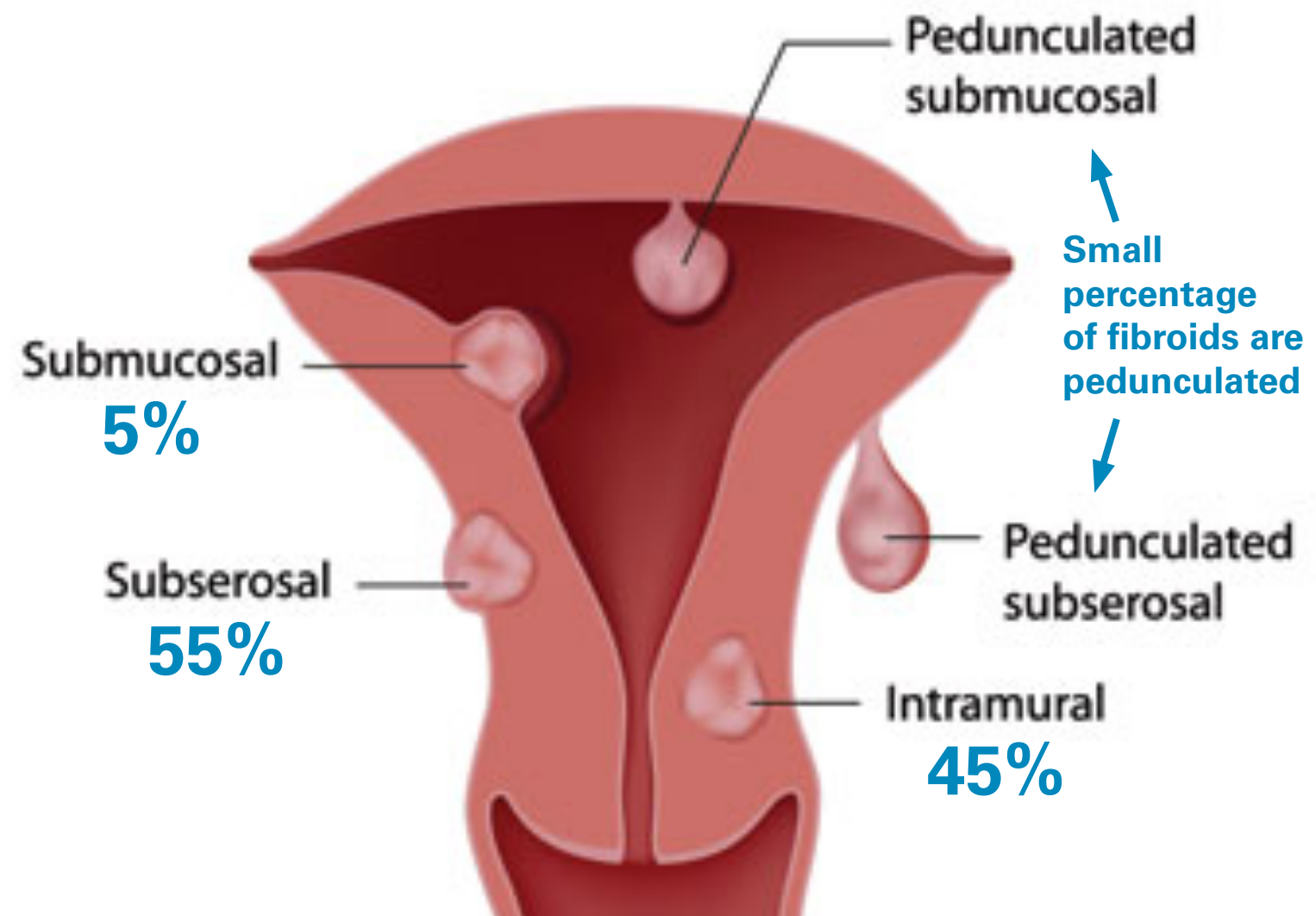
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Uterine Fibroids | Uterine Anatomy with Fibroids



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LEARN MORE

Uterine Fibroids | How to Read the MRI

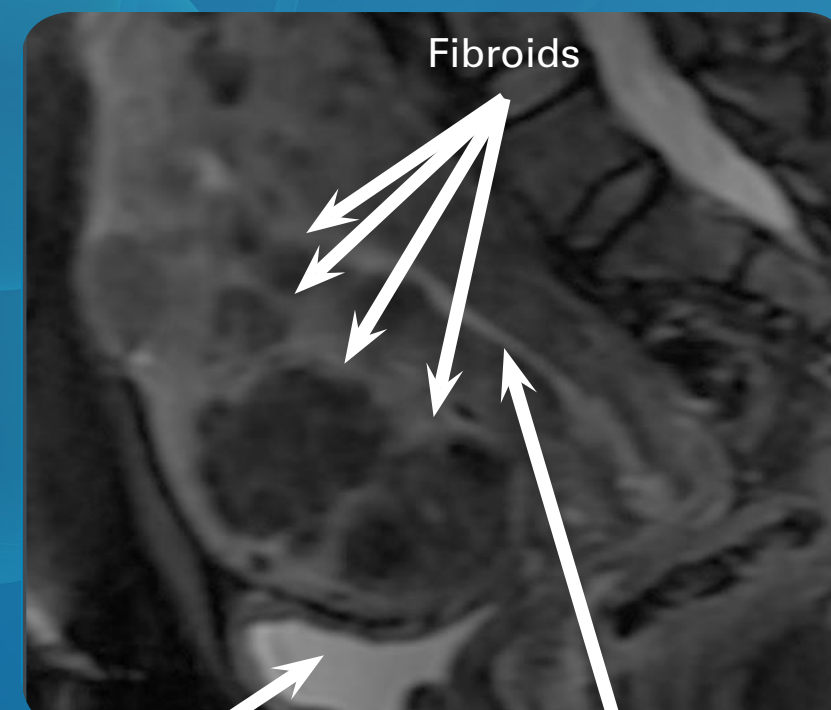
Normal Uterus on MRI



Bladder

Endometrial Cavity

Uterus with Fibroids



Bladder

Endometrial Cavity



UTERINE FIBROIDS

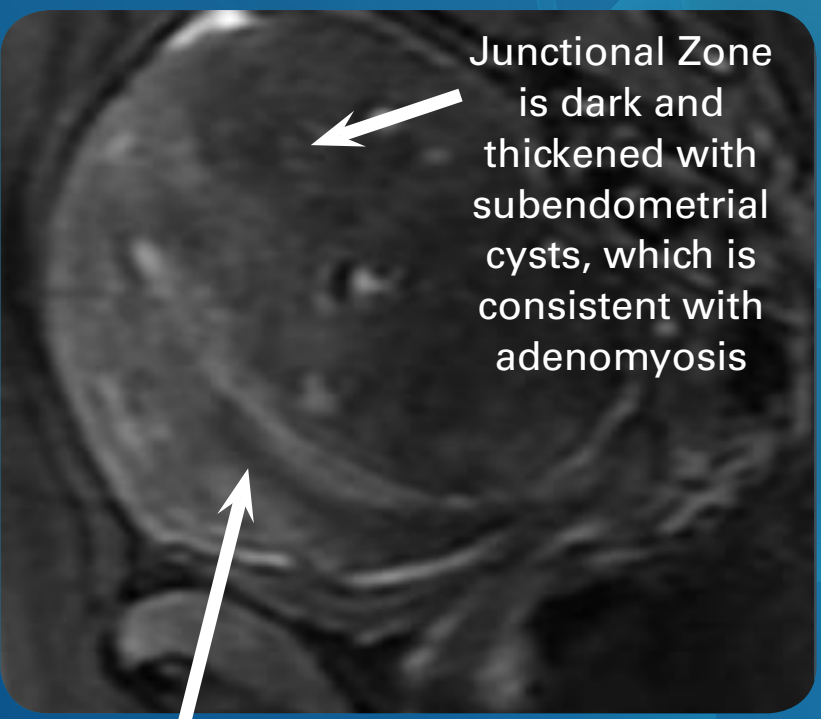


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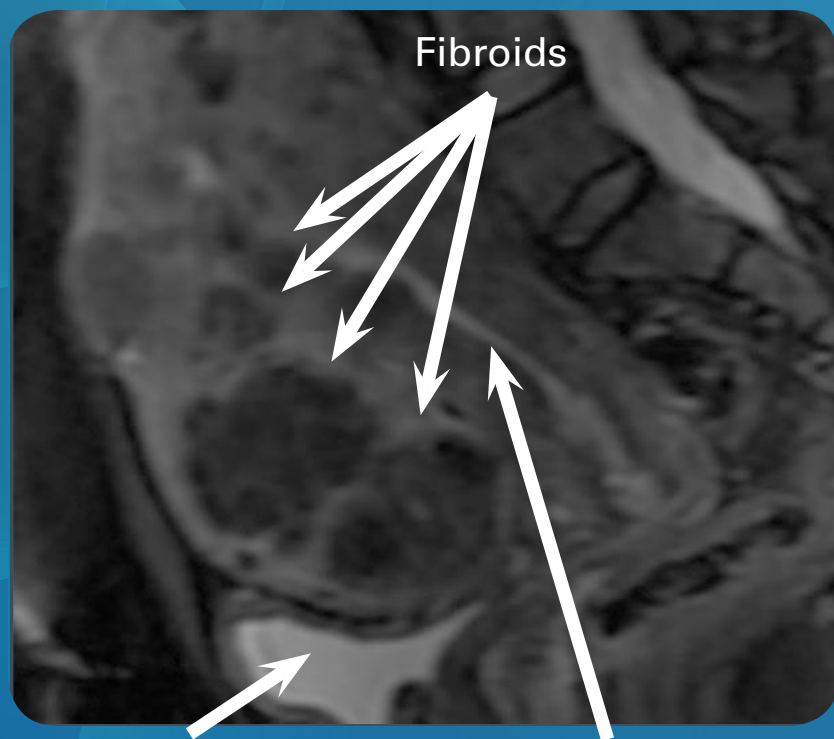
Uterine Fibroids | How to Read the MRI

Uterus with Adenomyosis



Endometrial Cavity (No Fibroids Present)

Uterus with Fibroids



Bladder

Endometrial Cavity



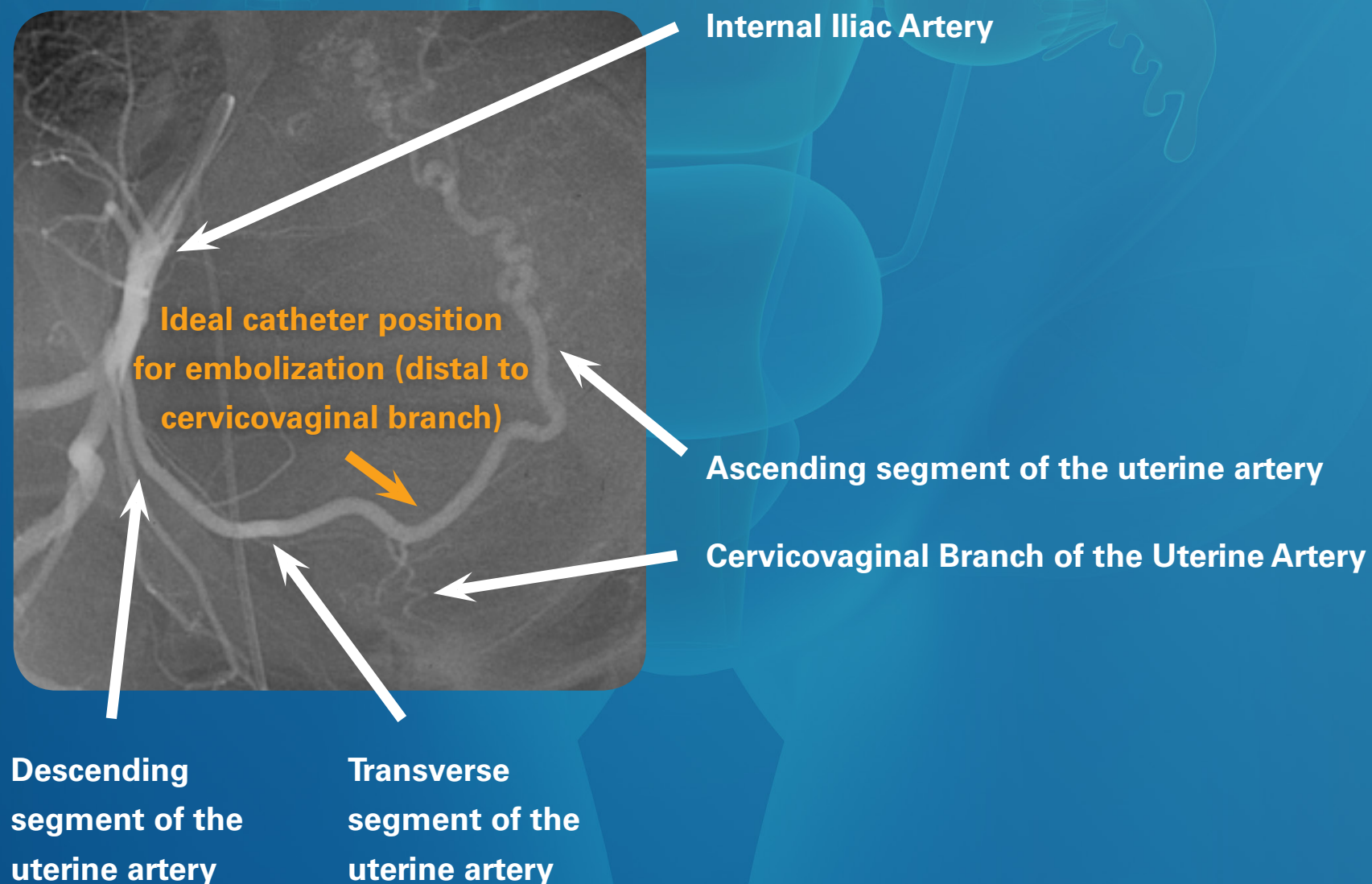
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Uterine Fibroid Embolization (UFE) | Uterine Artery Anatomy



UTERINE FIBROIDS

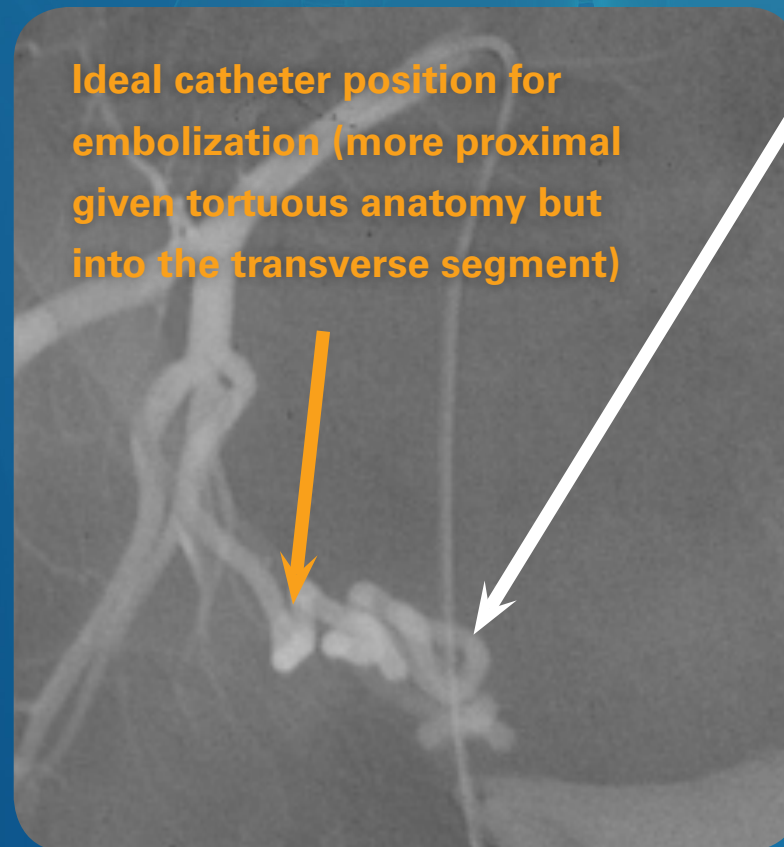


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Uterine Fibroid Embolization | Tortuous Uterine Artery

Ideal catheter position for embolization (more proximal given tortuous anatomy but into the transverse segment)



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.



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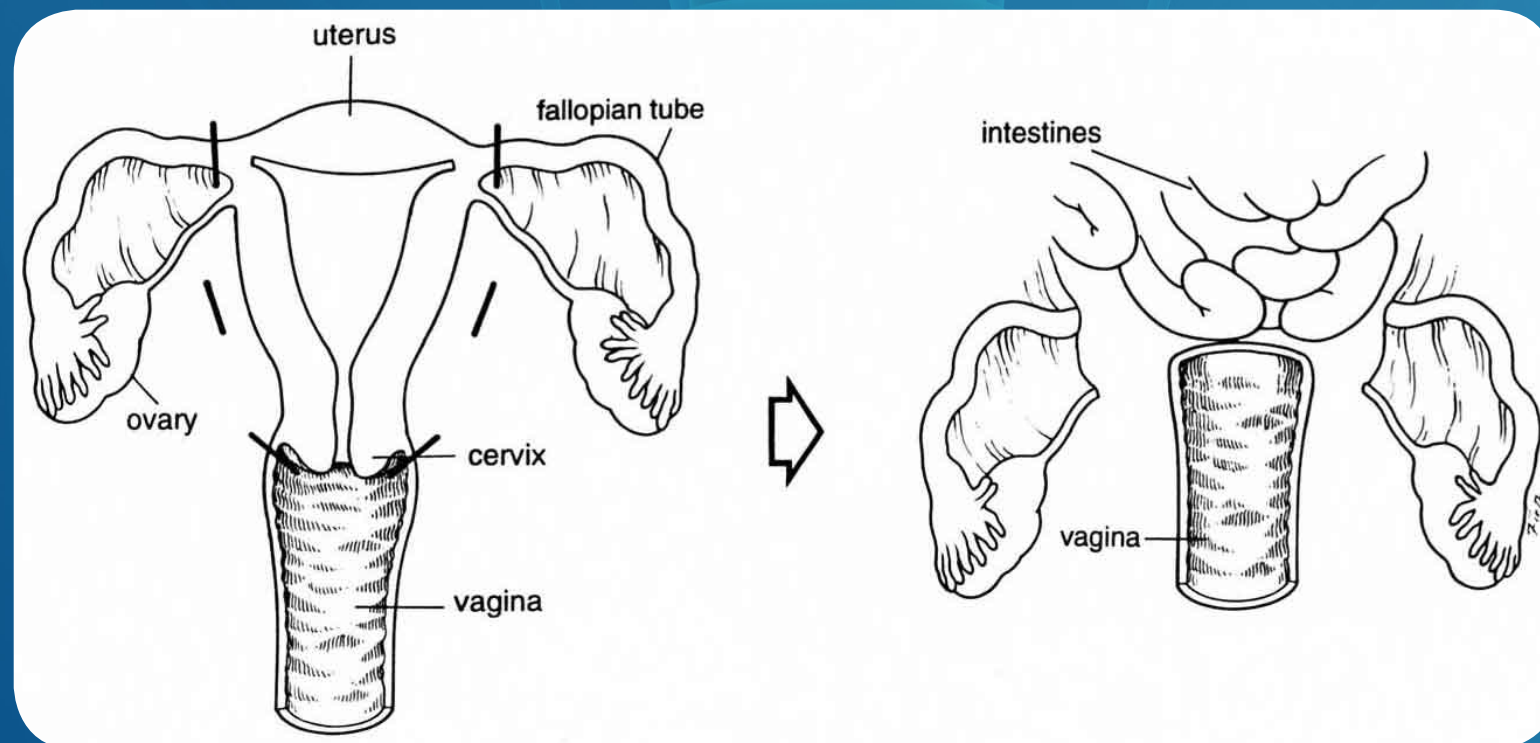
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 - ☒ Hysterectomy
 - ☐ Myomectomy
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LEARN MORE

Uterine Fibroids | Hysterectomy

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.



About half of the 600,000 hysterectomies performed in the U.S. each year are due to fibroids



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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



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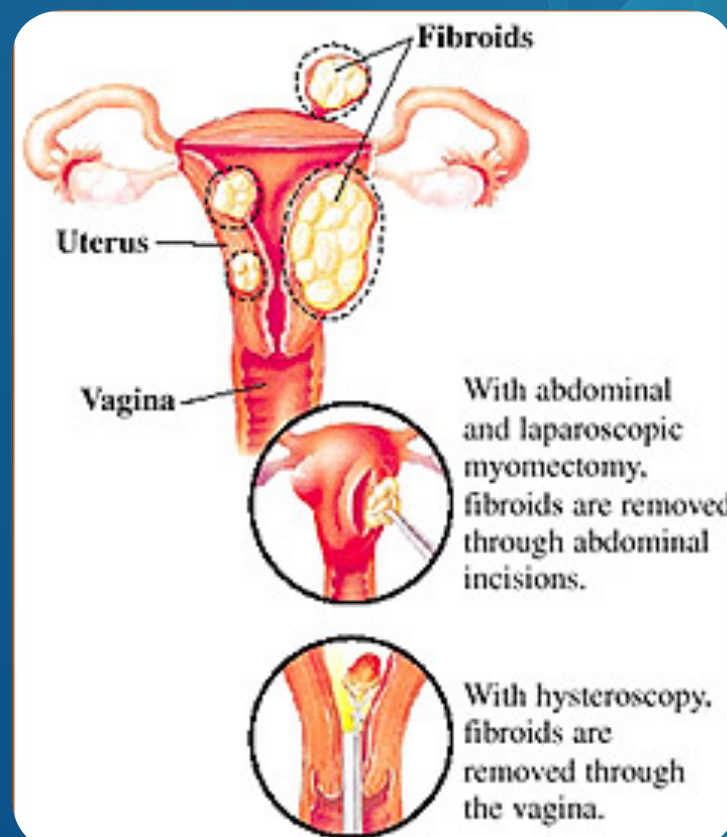
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Uterine Fibroids | Myomectomy

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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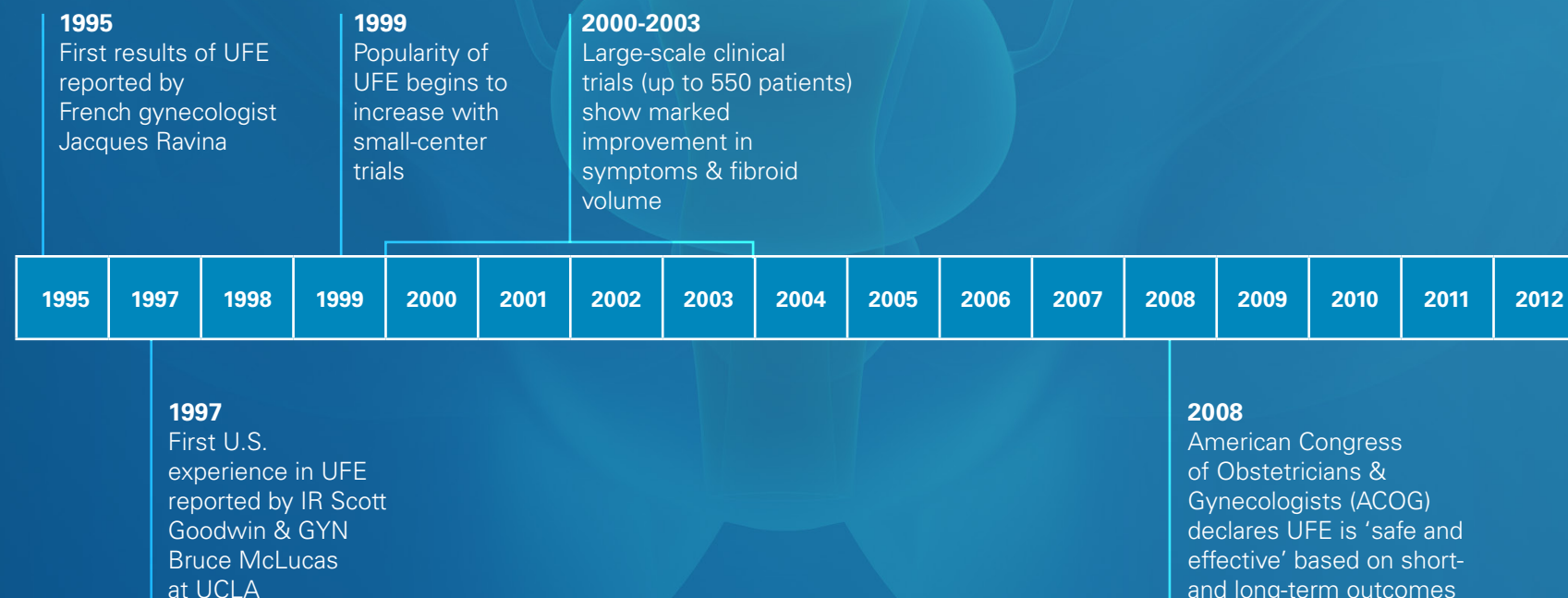


UFE | History & Development

Estimated UFE Procedures in 2015

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

United States	28,000	Global	95,000
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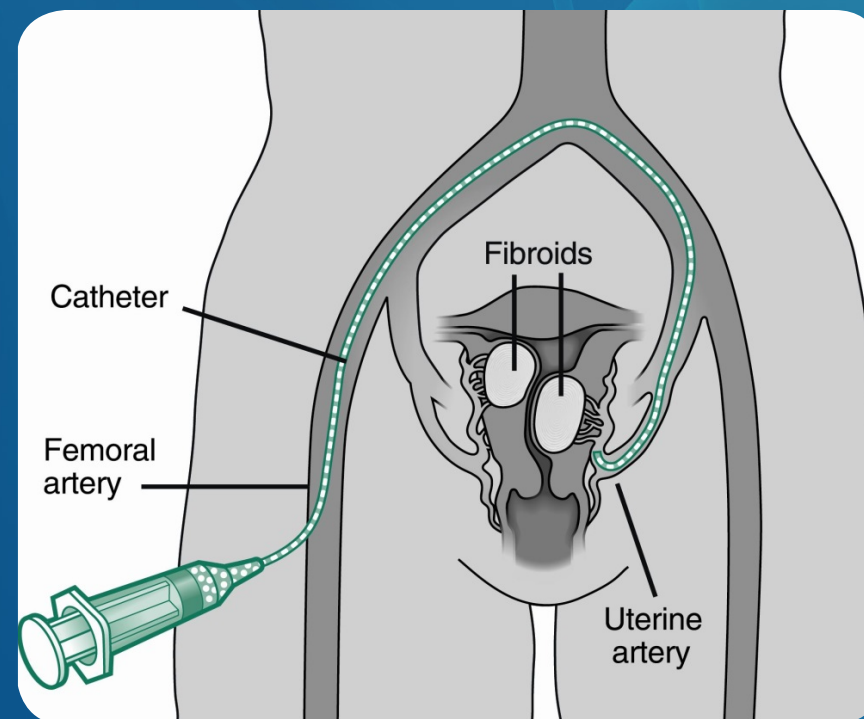
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Uterine Fibroid Embolization (UFE) | Overview

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.

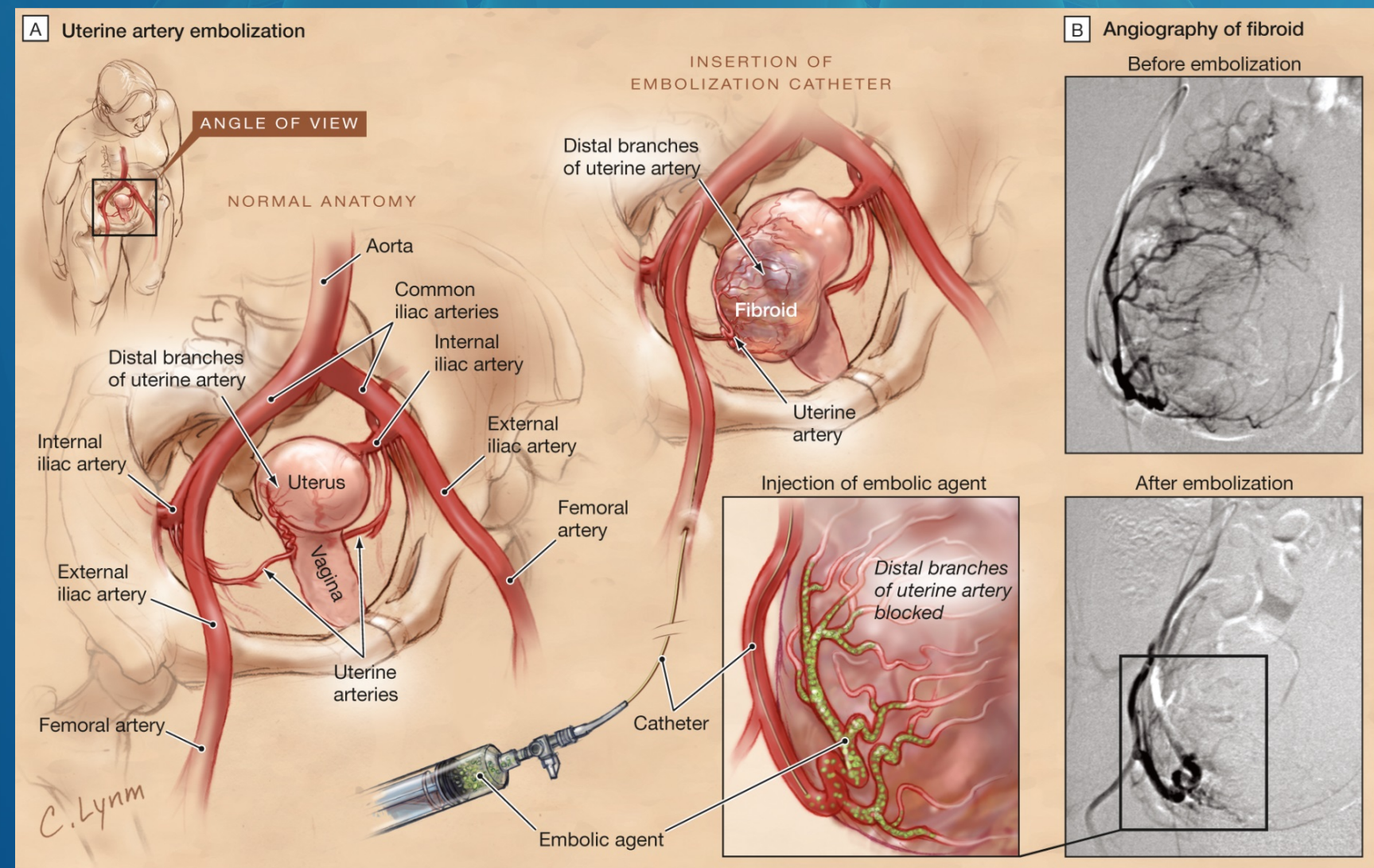
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Uterine Fibroid Embolization (UFE) | How to Perform UFE



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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

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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.

PVA Flakes

Tris-acryl Gelatin Microspheres

Embozene



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Uterine Fibroid Embolization (UFE) | Embosphere Microspheres

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



Stampfl Study, CVIR 2010¹

Clinical Results	Embosphere™ Microspheres
Number of Patients	121
Volume Reduction of Dominant Fibroid at 1-Year Follow-Up	91%
Improved Hypermenorrhea at 2-Year Follow-Up	94%
Improved Dysmenorrhea at 2-Year Follow-Up	95%
Patient Satisfaction (-3 = Not satisfied at all to +3 = Perfect satisfaction)	+2.7



Smeets Study, JVIR 2010²

Clinical Results	Embosphere™ Microspheres
Number of Patients	86
Patients with 100% complete infarction in dominant fibroid	69
Patients with greater than 90% infarction in dominant fibroid	81
Health-Related Quality of Life Score (HRQOL) Before UAE with Embosphere (Asymptomatic population score = 86)	53
HRQOL at 1-Year Follow-Up after UAE with Embosphere	90

1. Stampfl, U., et al. Cardiovascular and Interventional Radiology (2010). 15 Oct. 2010.
2. Smeets, A., et al. Journal of Vascular and Interventional Radiology 21.12 (2010): 1830-834.

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

Embosphere® Microspheres	Clinical Results	Contour™ PVA Particles
3.2	Change in Bleeding Score	3.3
21.3	Fibroid-Specific Symptom Score	23.4
81.9	Quality of Life Total Score	80.9
23%	Presence of Uninfarcted Fibroid (%)	24%
20%	Presence of Complications	17%

Embosphere® Microspheres	Procedural Results	Contour™ PVA Particles
9.4	Embolic Volume/Patient (ml)	3.0
4%	Frequency of Catheter Occlusion (%)	28%

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."

* Spies, et al. PVA Particles vs. Tris-acryl Microspheres for UAE, JVIR Aug 2004.

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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 FIBROIDS



Select from these topics

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 - ☐ Overview
 - ☐ UFE Procedure Illustration
 - ☐ IR Technique
 - ☐ Embolic Agents
 - ☐ Embozene Microspheres
 - ☐ Microspheres vs. PVA
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LEARN MORE

Uterine Fibroid Embolization (UFE) | Complications & Risks*

Other Complications After UFE

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

Age at UFE	Amenorrhea after 3 years	Amenorrhea after 6 years
< 40	0%	0%
40 – 44	1.4%	11.2%
> 44	19.7%	40.4%

*Katsumori, et al. Int J Gynaecol Obstet 2008



UTERINE FIBROIDS



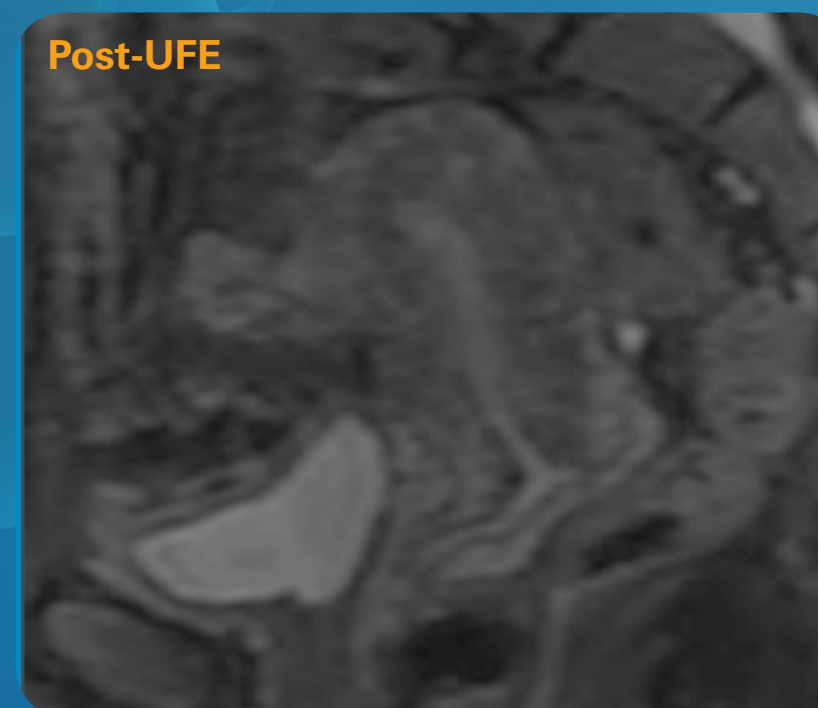
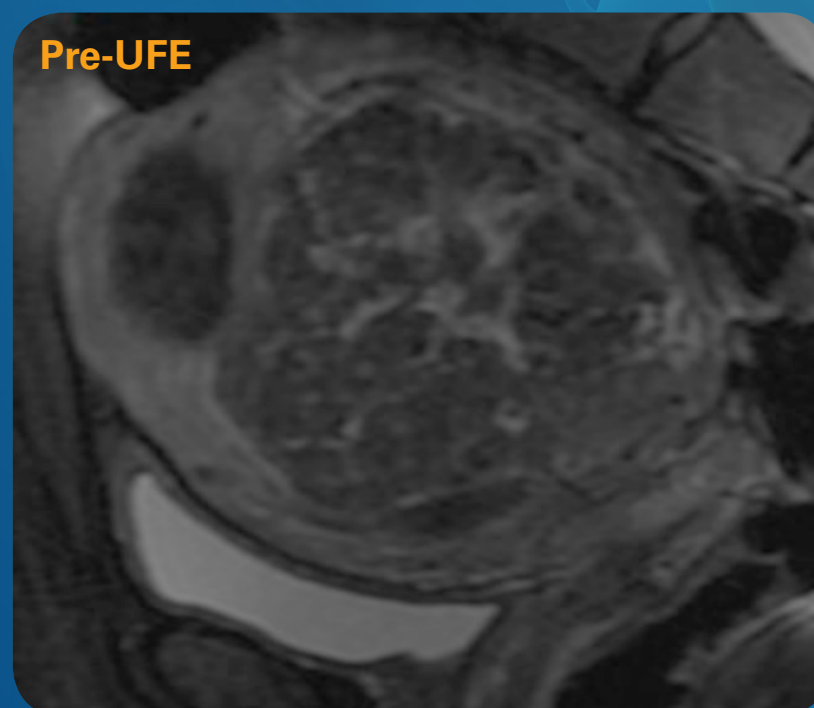
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Uterine Fibroid Embolization (UFE) | Complications & Risks*

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%).



Large fibroid passed on its own after embolization

Images provided by Gary Siskin, MD.
* Shlansky-Goldberg RD, et al. J Vasc Interv Radiol 2011; 22:1586.

[Full list of References]



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Uterine Fibroid Embolization (UFE) | Patient Selection

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



Against UFE



- | | |
|--|--|
| <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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) |
|--|--|



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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.

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 - ☒ Symptom Improvement
 - ☐ Fibroid Volume Reduction
 - ☐ Fibroid Infarction
 - ☐ Fertility

UFE Clinical Outcomes | Symptom Improvement^{1,2}

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)

	Initial Score Before UFE	6 Months after UFE	12 Months after UFE	Normal Population
Symptom Control Score	59.8	19.8	19.2	22.5
Health-Related QOL Score	47.3	85.0	86.7	86.4

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



1. Scheurig-Muenkler C, et al. Hum Reprod 2011; 26:2036. 2. Poulsen B, et al. Acta Obstet Gynecol Scand 2011; 90:1281

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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%*

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



UTERINE FIBROIDS



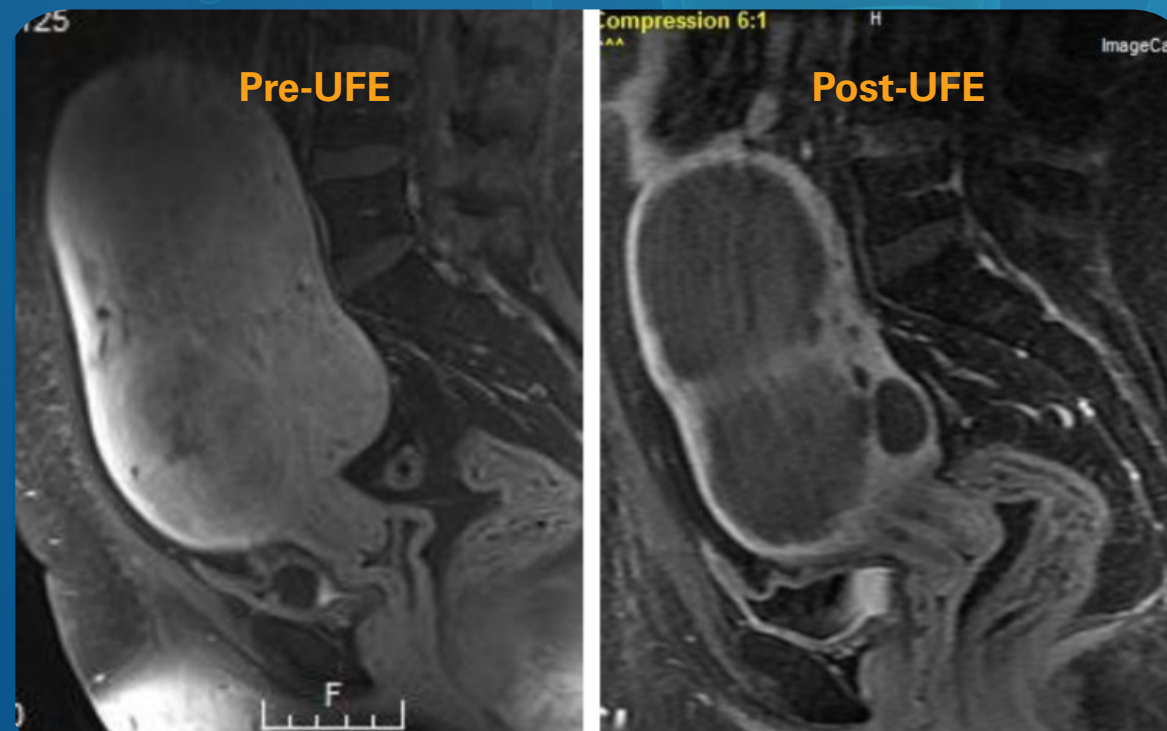
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LEARN MORE

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



UTERINE FIBROIDS



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UFE Clinical Outcomes | Fibroid Infarction

Key Takeaway: More infarction is correlated with better outcomes.

% Fibroid Infarction	Patients	Rate of Symptom Control	Rate of Additional GYN Intervention
100%	142	93% ↑	3% ↓
90 – 99%	74	71%	15%
<90%	5	60%	20% ↓



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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).¹

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.²
- 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.

1. Pisco JM, et al. Fertil Steril 2011; 95:1121. 2. Mara M, et al. Cardiovasc Interv Radiol 2008; 31:73

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.

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