

Uterine Fibroid Embolization

Optimum Patient Care

Dr. Francis Fernandez, Jr.
Radiology Specialists of Florida

Agenda Overview

UFE History, Fibroid Anatomy and Procedure

The Literature

Patient Selection

Working with Interventional Radiology

Q & A

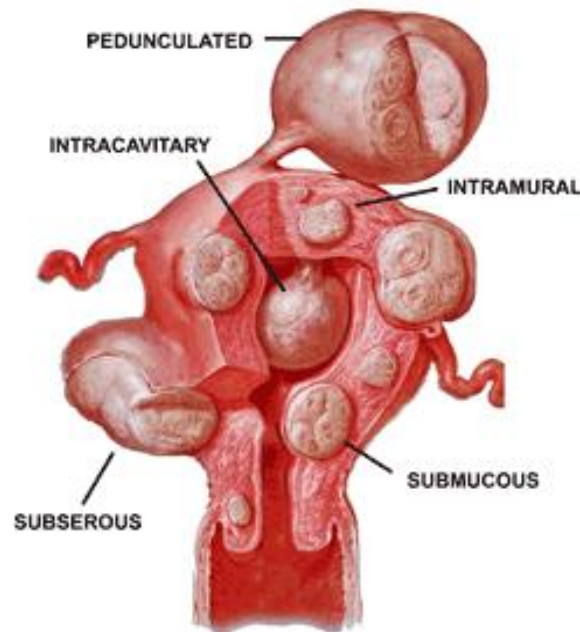
UFE History, Fibroid Anatomy and Procedure

History of Uterine Fibroid Embolization (UFE)

- 1995 Ravina - France
 - 16 patients (34-48 yrs)
 - 100% technical success
 - 20 month follow-up
 - 11 complete response
 - 3 partial improvement
 - 2 failures
 - 14 experienced pelvic pain
 - "Arterial embolization to treat uterine myomata," *Lancet* 346[8976]:671-672, 1995
- First UFE in the U.S. – 1997 at UCLA with Scott Goodwin, MD and Bruce McLucas, MD
 - "Preliminary experience with uterine artery embolization for uterine fibroids," (S.C. Goodwin, et al., *Journal of Vascular and Interventional Radiology* 8[4]:517-526, 1997)
 - "Uterine artery embolization for the treatment of uterine leiomyomata midterm results," (S. C. Goodwin, et al., *Journal of Vascular and Interventional Radiology* 10[9]:1159-1165, 1999)

Uterine Leiomyoma (Fibroids)

- Benign tumors that develop in uterus
- Can cause problems because of their size and location
- Typically improve after menopause



Symptoms

- Depending on location, size and number
 - Heavy, prolonged menstrual periods-anemia
 - Pelvic pain
 - Pelvic pressure or heaviness
 - Pain in the back or legs
 - Pain during sexual intercourse
 - Bladder pressure – constant urge to urinate
 - Pressure on bowel, constipation, bloating
 - Abnormally enlarged abdomen

Patient Demographics

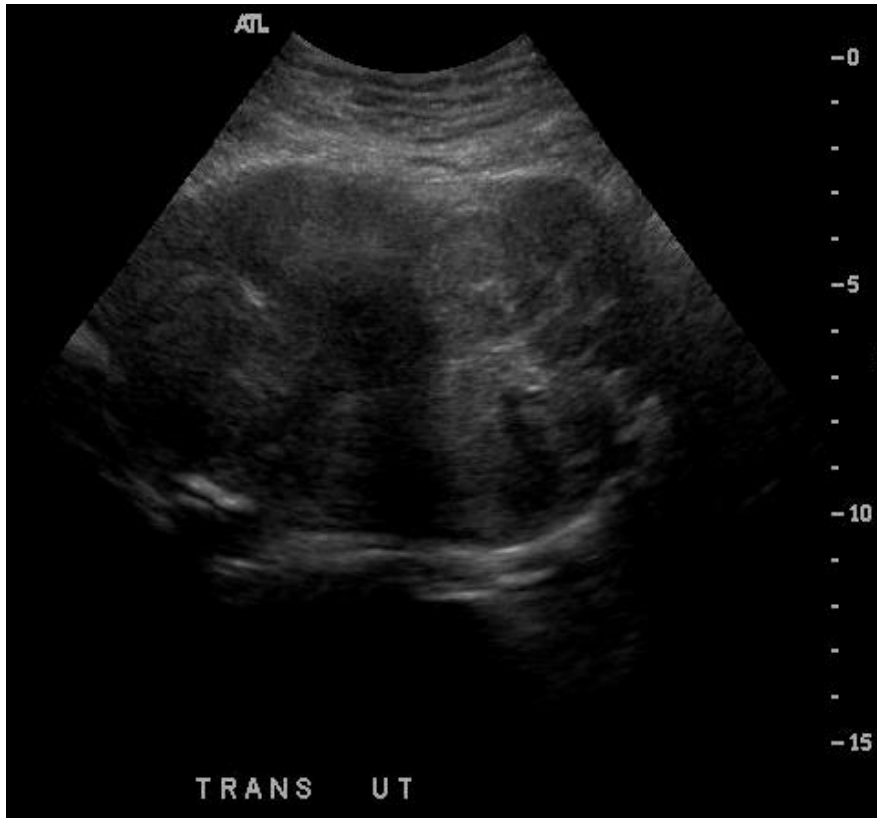
Incidence increases with age

- 20% of women in their 20's
- 40% of women in their 40's

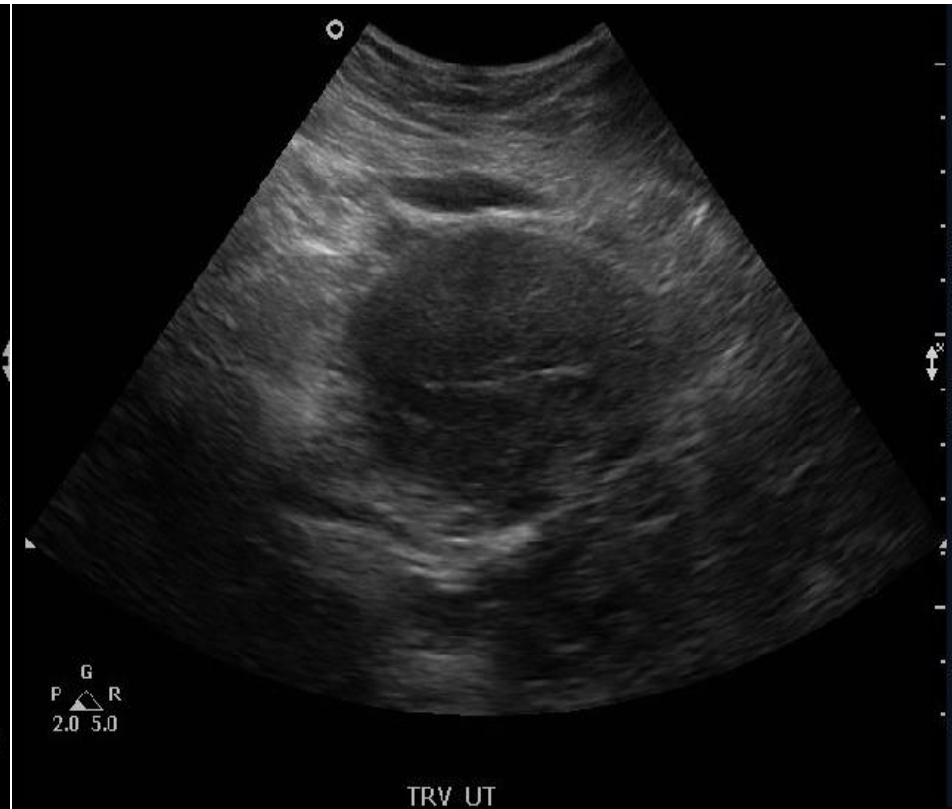
Genetic predisposition

- African-American women at higher risk
- Familial tendencies

Imaging- Sonography



Multiple Fibroids



Normal Uterus

6:20:46 pm

ML CRNL

EV-8C4

7.0MHz

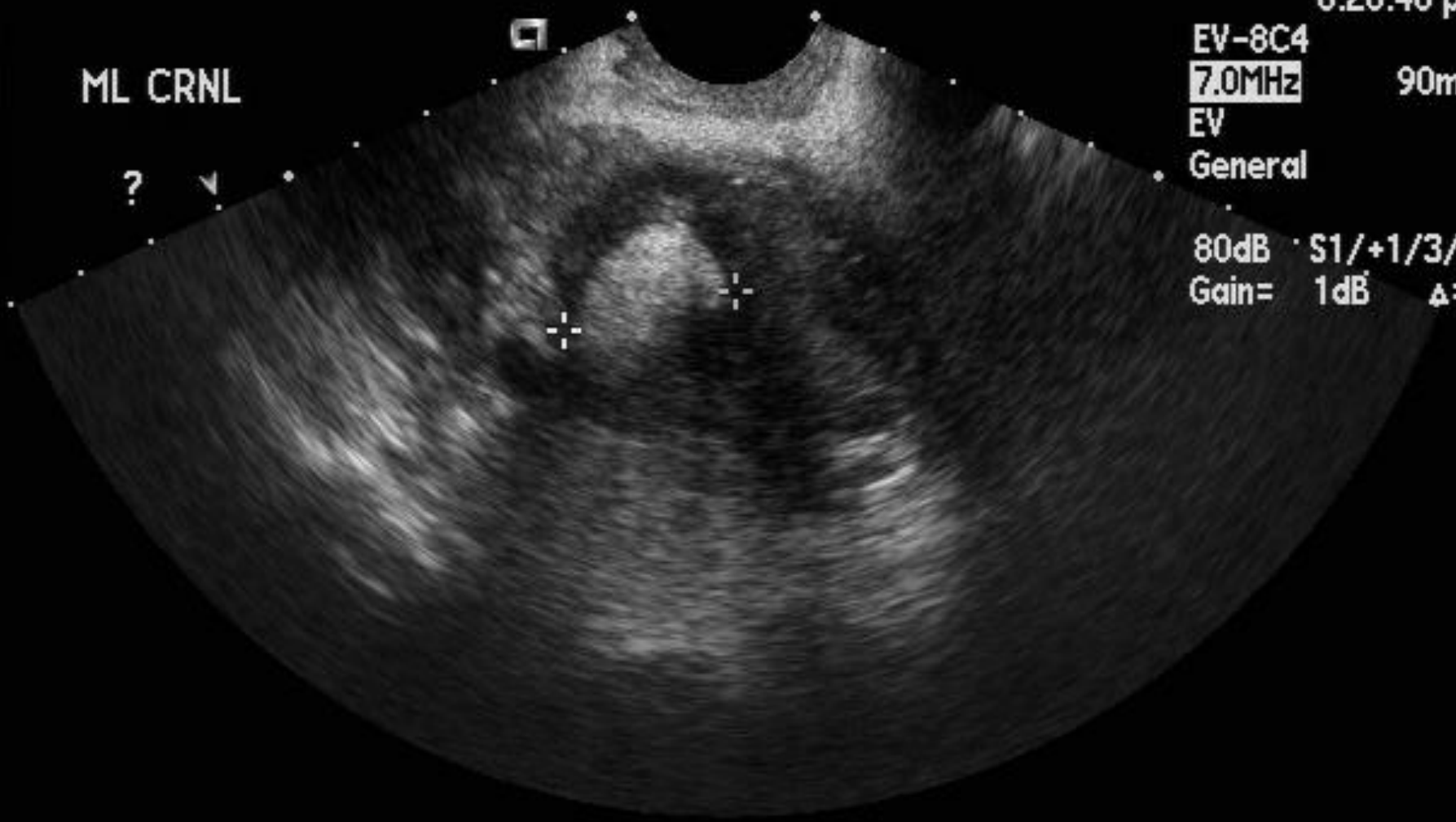
90mm

EV

General

80dB S1/+1/3/4

Gain= 1dB Δ=2

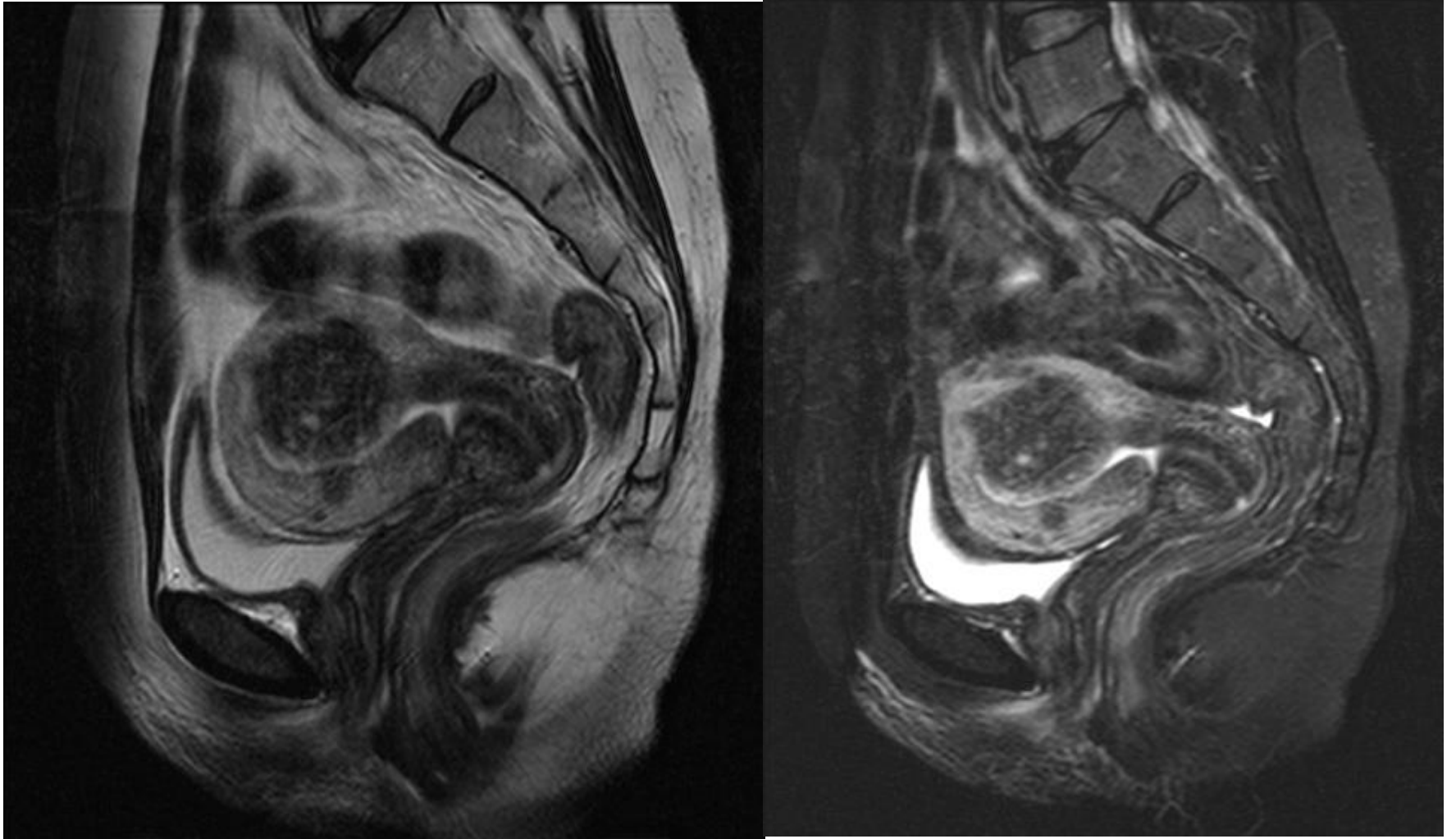


Dist = 2.34cm

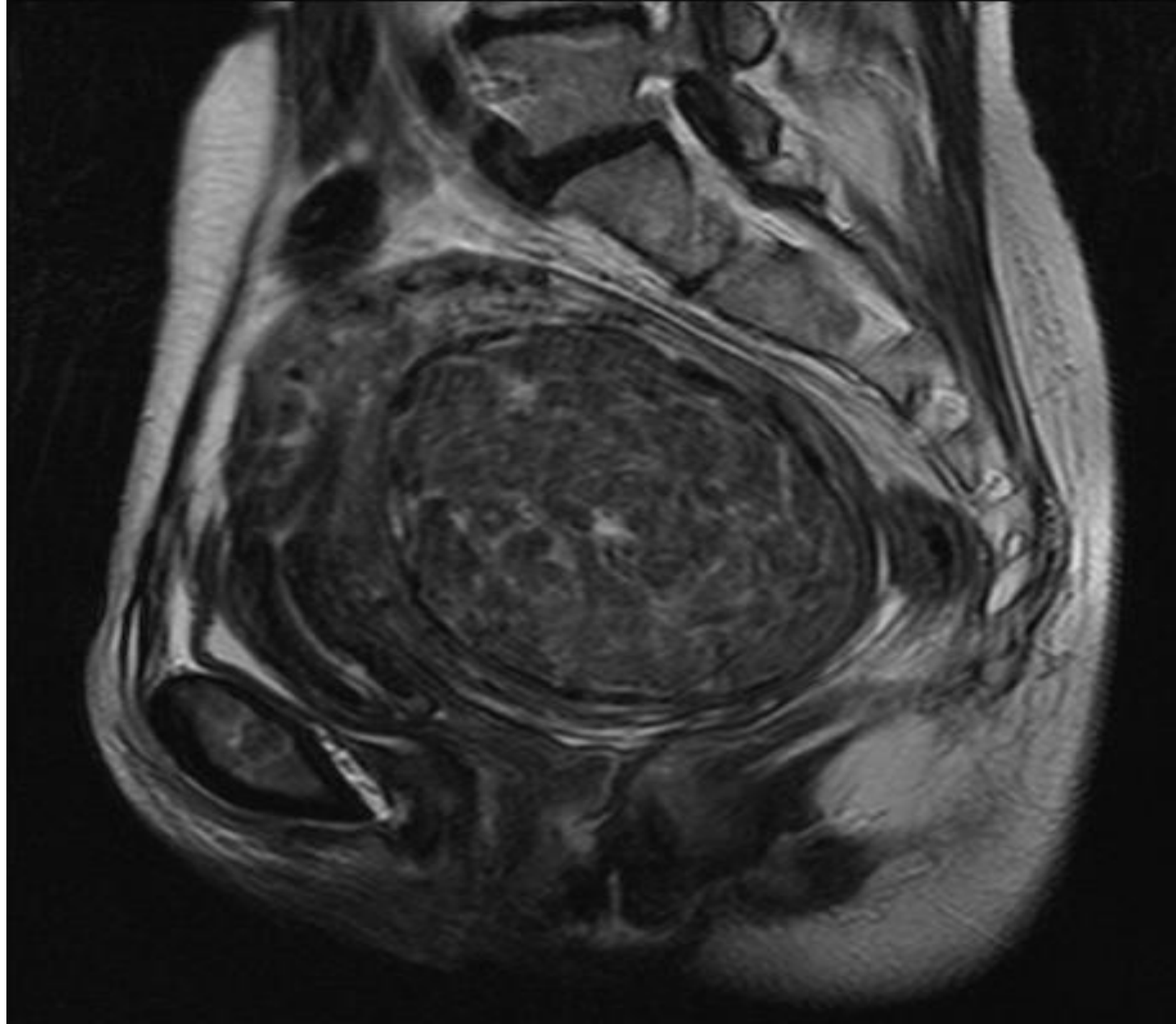
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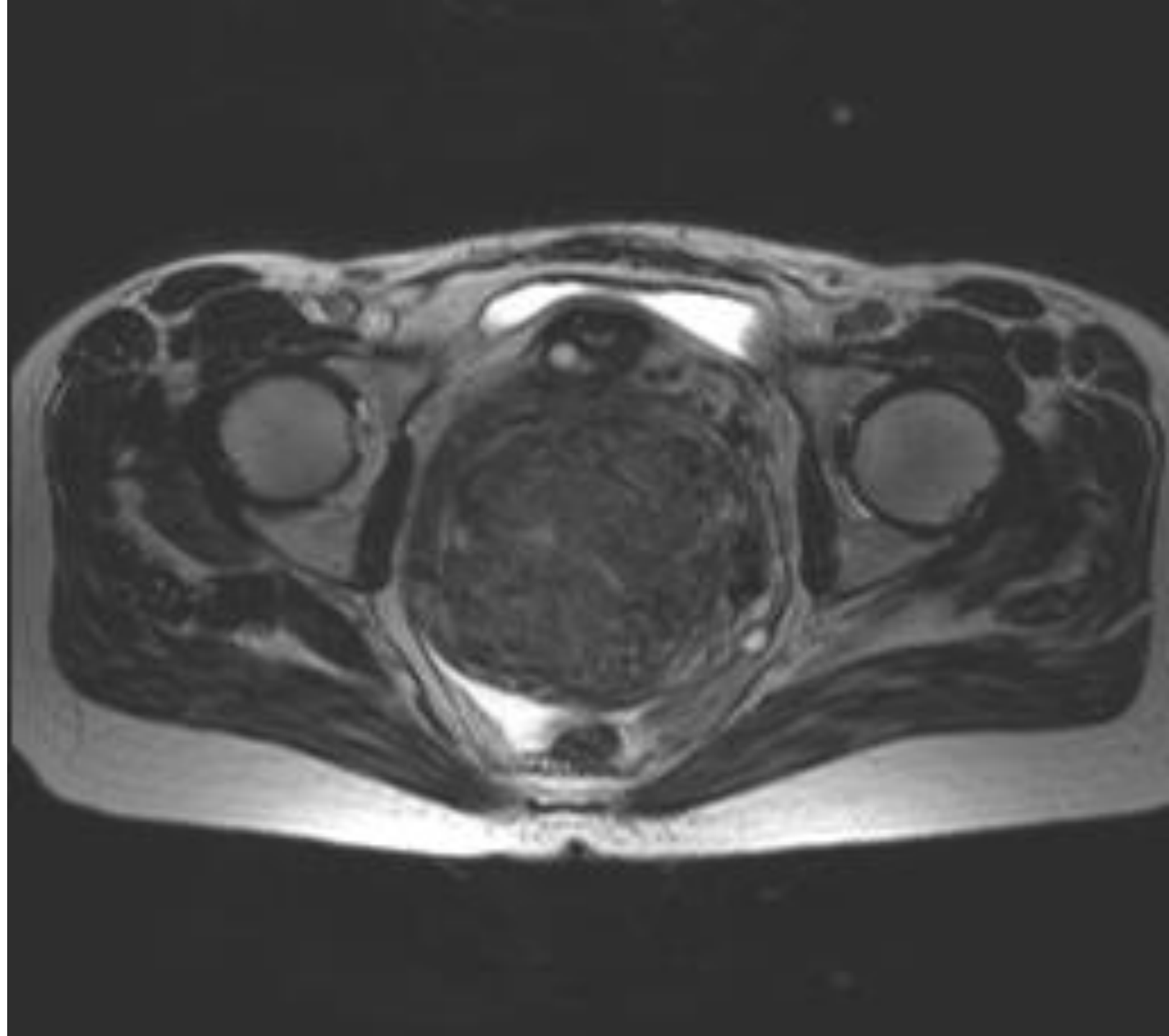
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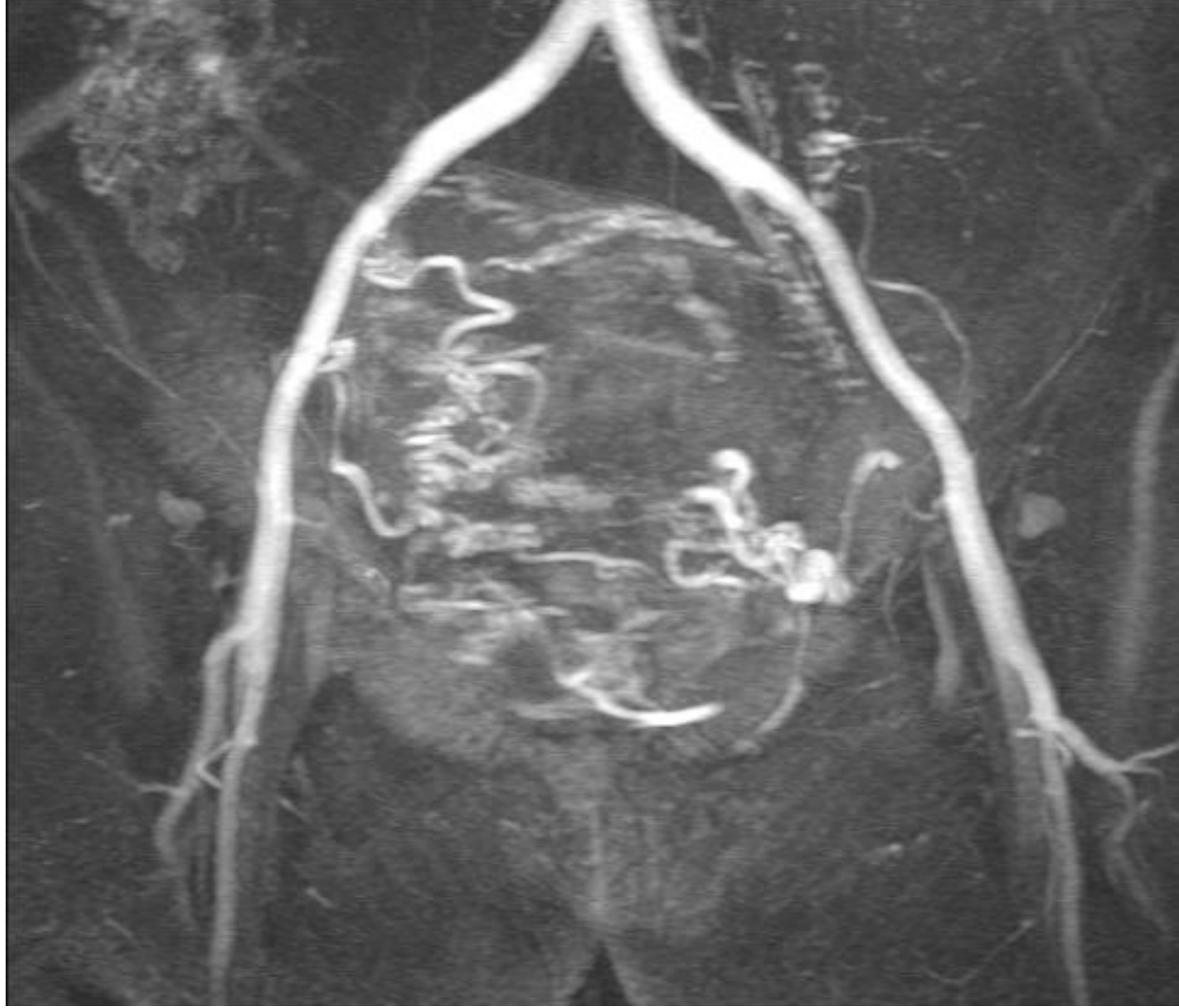
Imaging - MRI



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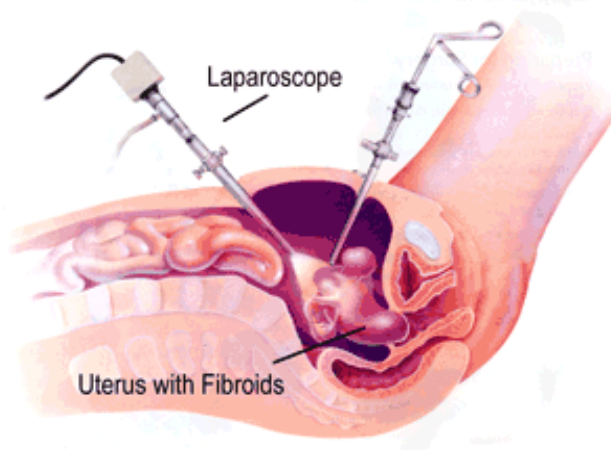
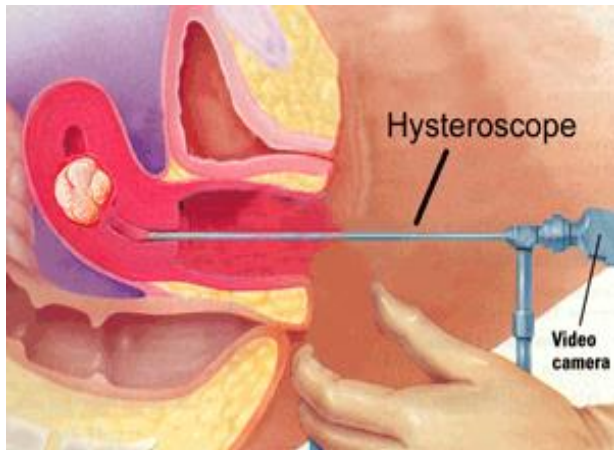


Treatment

- Most fibroids do not cause symptoms and are not treated
- Medical Treatment
 - Birth-control pills or other hormonal therapy
 - Non-steroidal anti-inflammatory drugs (Ibuprofen or naproxen)
 - Fibroids often regenerate after therapy is discontinued

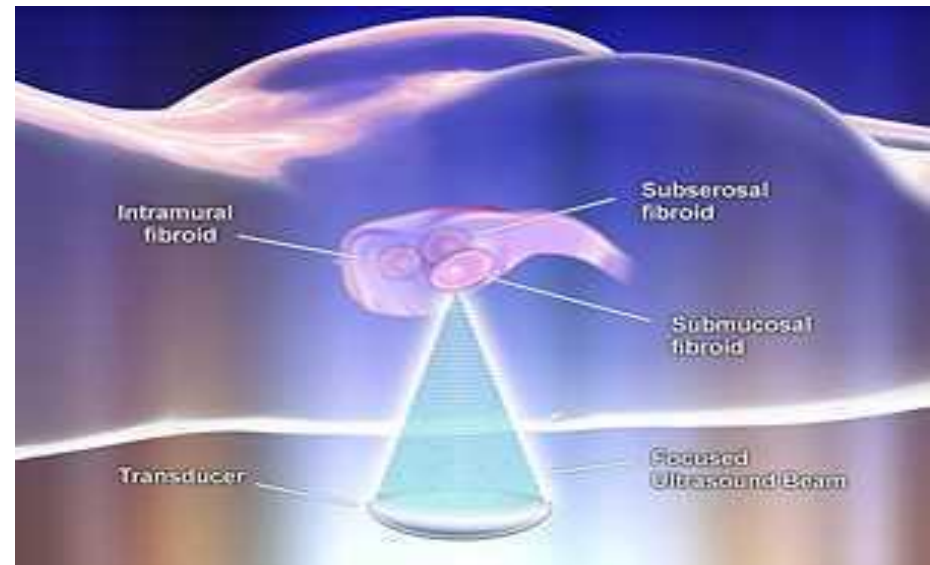
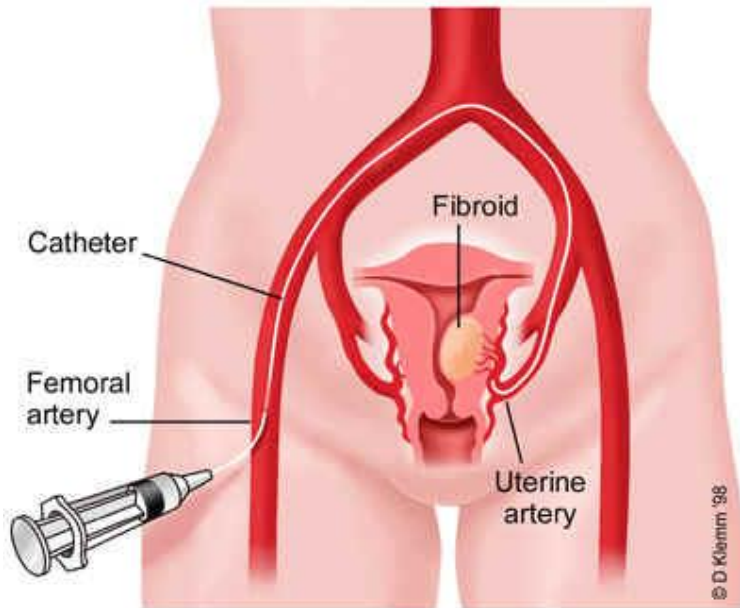
Surgical Treatment

- Myomectomy
- Hysterectomy



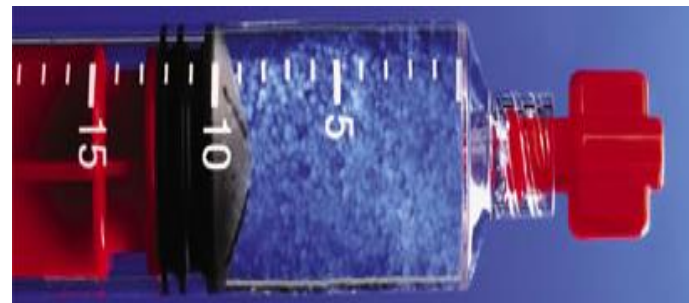
Treatment

- Image-Guided Treatment
 - High Frequency Focused Ultrasound
 - Uterine artery embolization



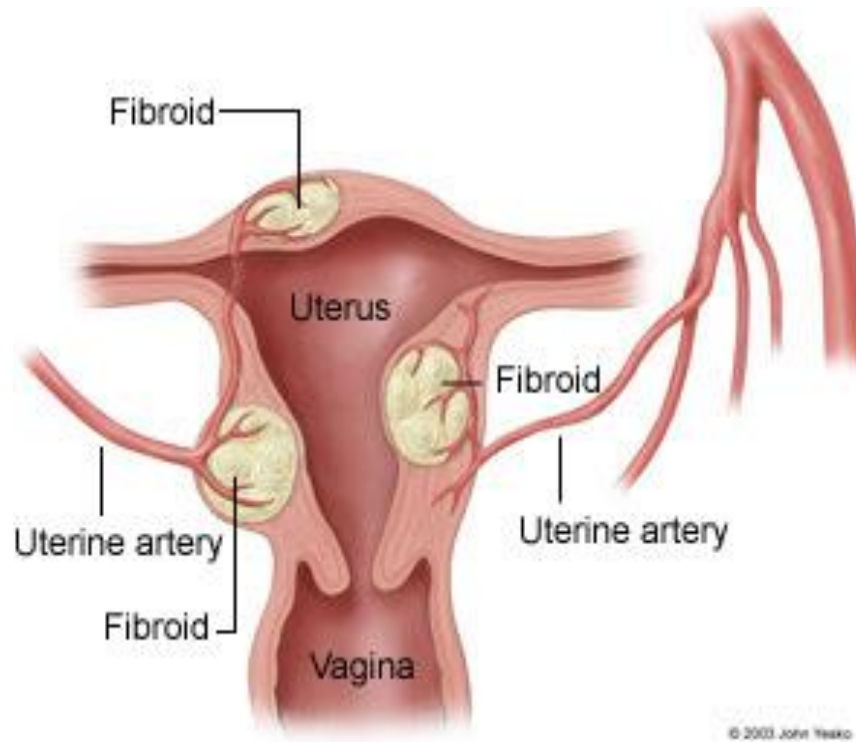
Uterine Artery Embolization

- Interventional Radiologist injects tiny plastic particles the size of grains of sand into the artery that supplies the fibroid
- Occludes blood flow and causes the tumor/s to shrink
- The artery on the other side of the uterus is then treated



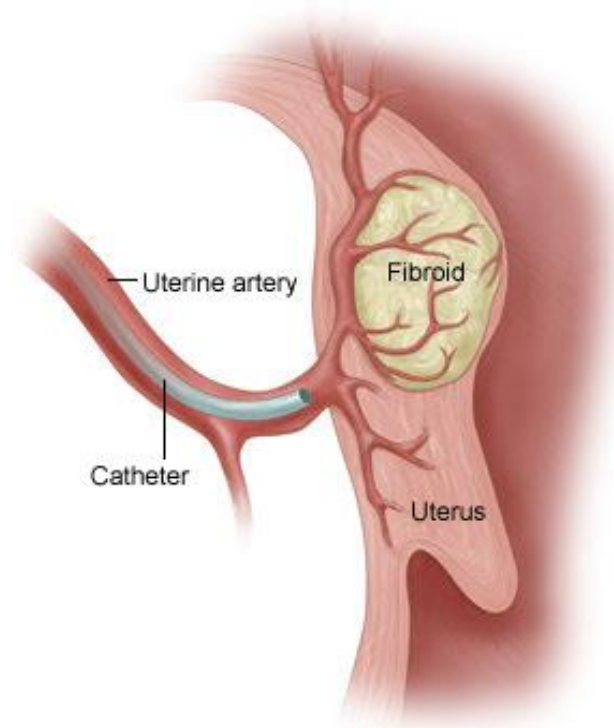
Uterine Artery Embolization

- Baseline imaging variables – US/MRI
 - Uterine volume
 - Largest leiomyoma volume and location
 - Number of leiomyomas



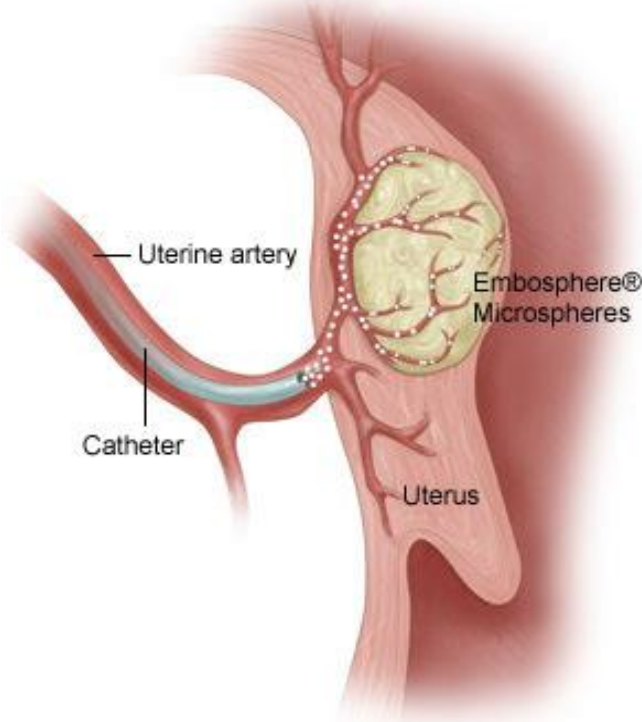
Uterine Artery Embolization

- Uterine artery catheterization
 - 5 F catheters
 - Microcatheters
 - small vessels or flow-limiting spasm



Uterine Artery Embolization

- Bilateral embolization
 - Polyvinyl alcohol particles (500 – 710 μ m)
 - Ivalon
 - Trufill
- Leiomyoma vasculature is occluded and slow flow or near stasis in main uterine artery



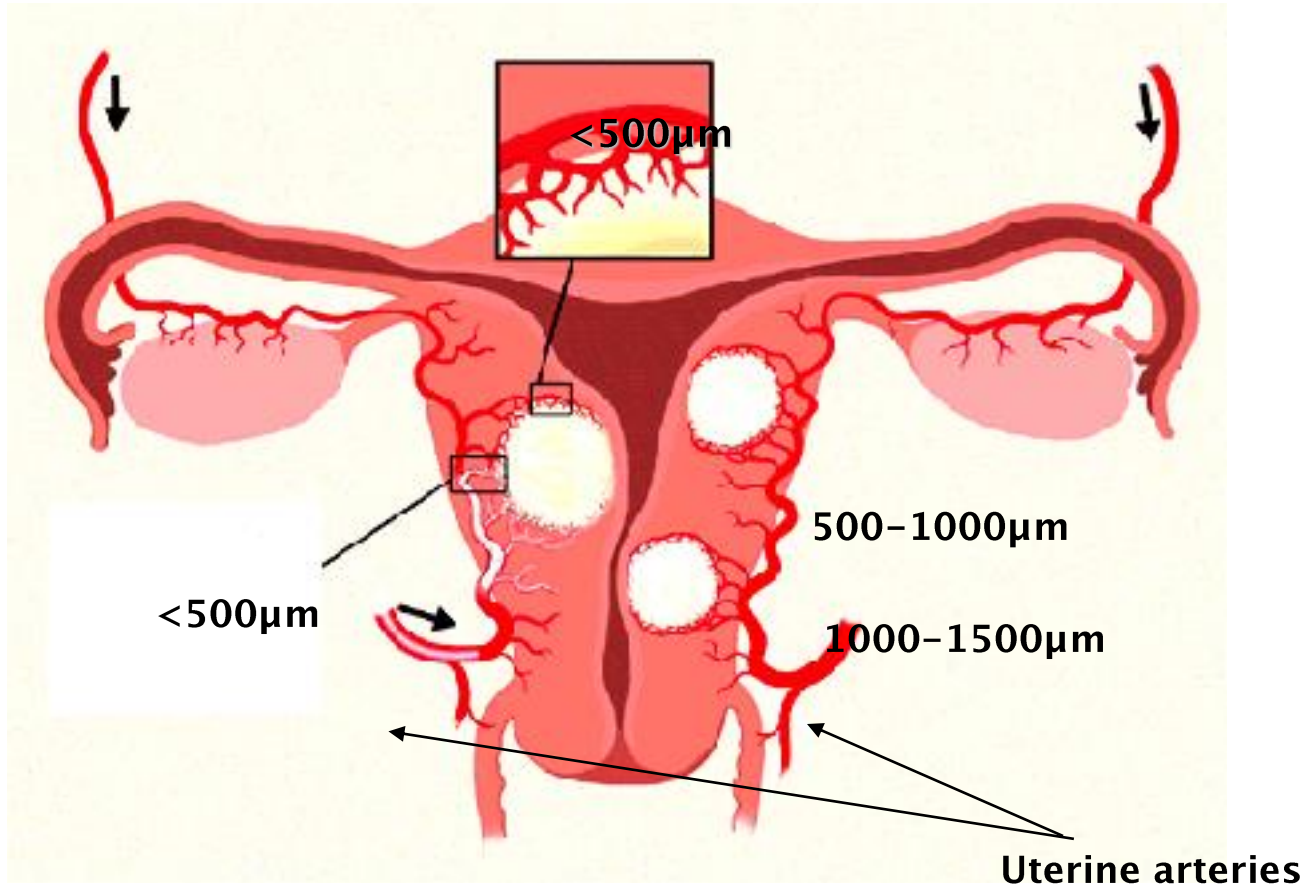
First FDA Cleared Embolic Indicated for Uterine Fibroids – November 2002



Embosphere® Microspheres

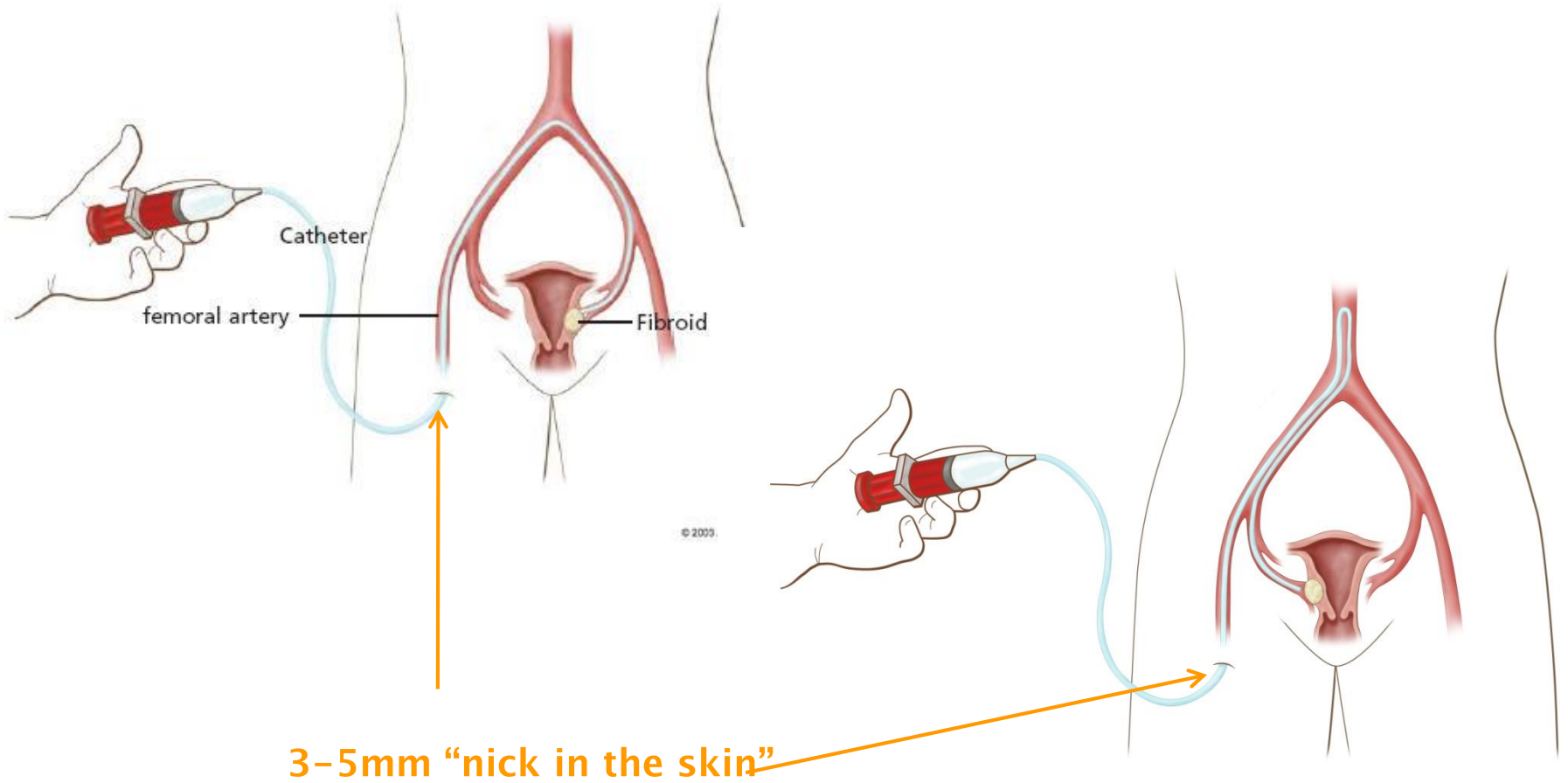
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Vascular Network of Uterine Fibroids



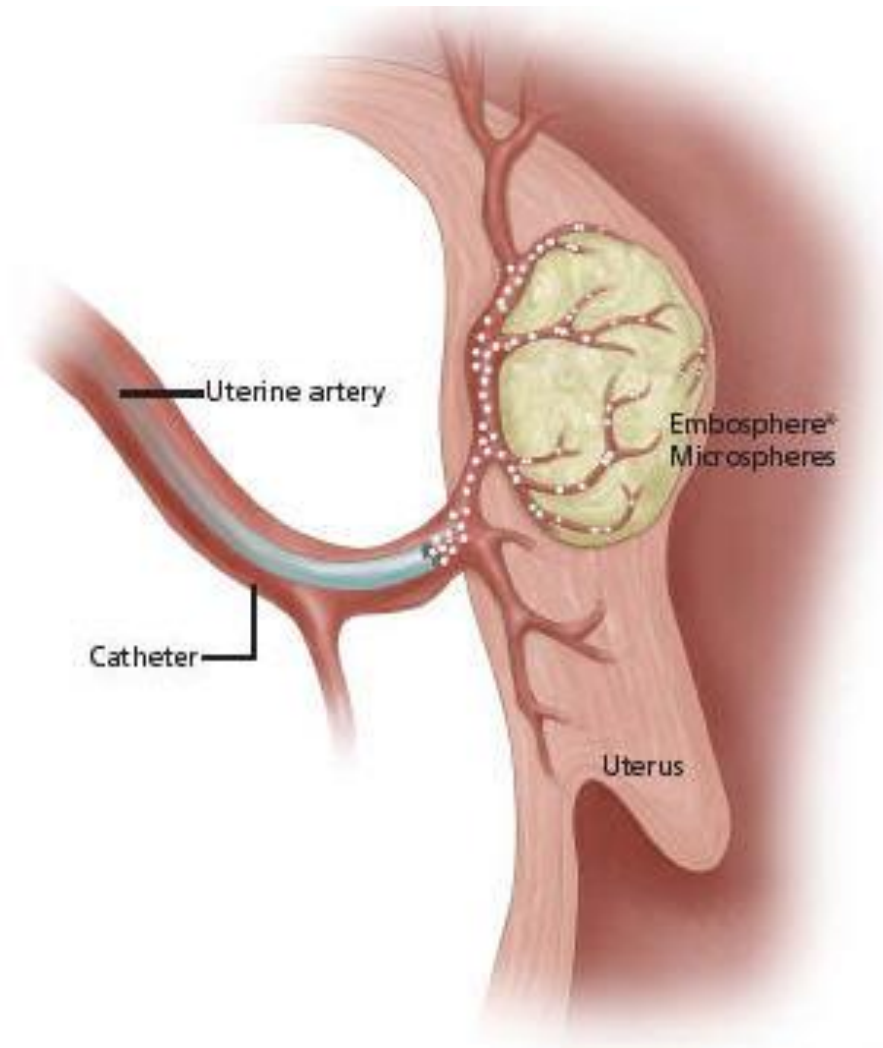
Arterial network measured in microns.

Accessing the Uterine Artery



© 2003 John Yesko

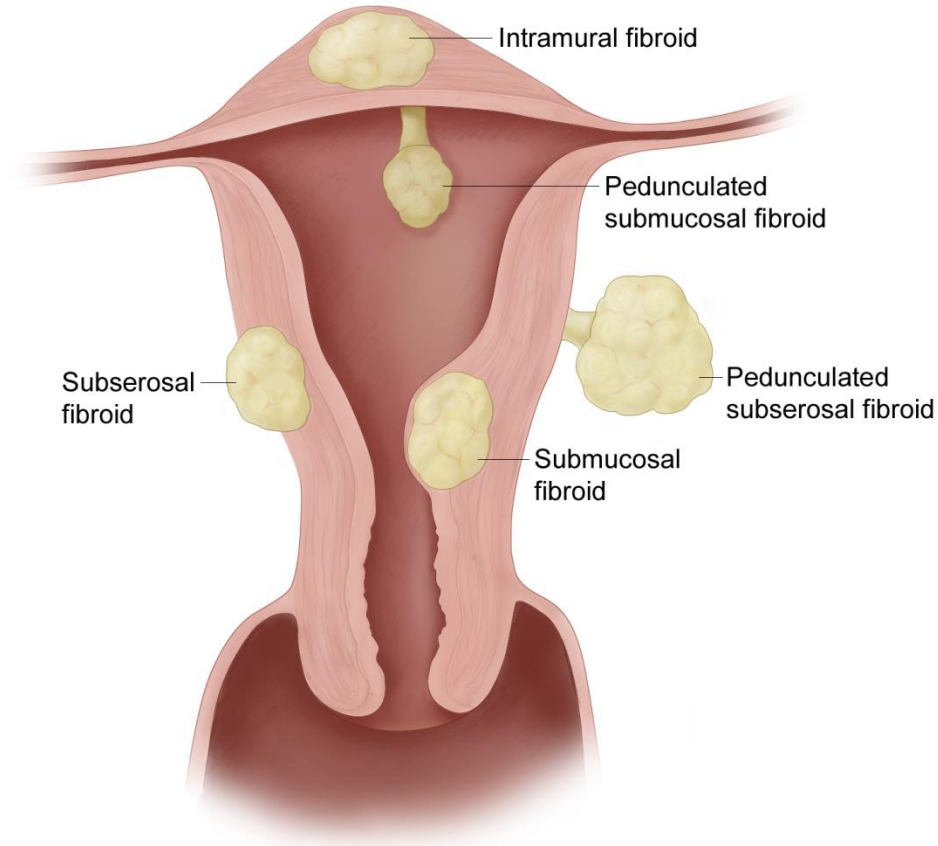
Arterial Inflow to Fibroids



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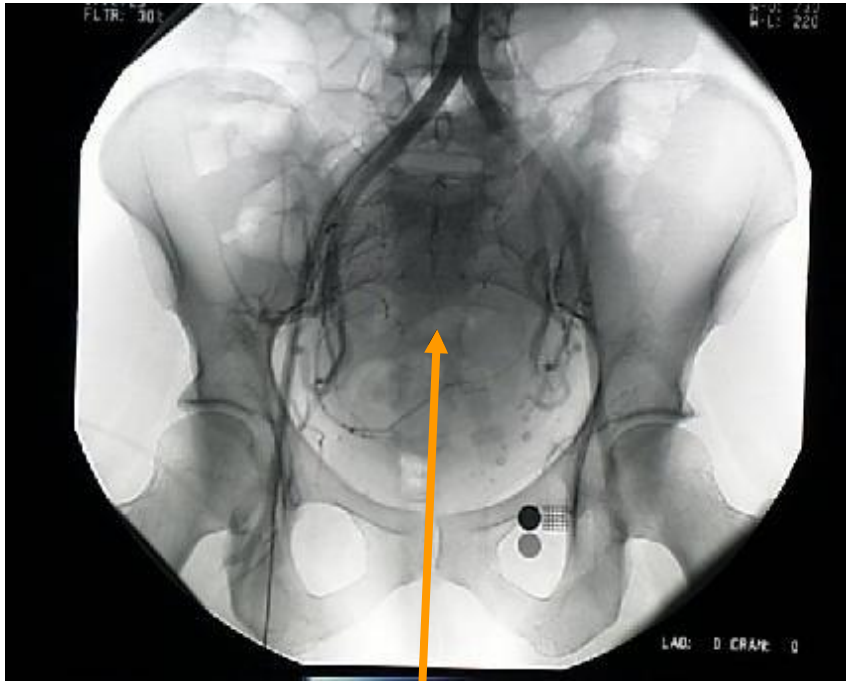
Types of Uterine Fibroids



© 2003 John Yesko

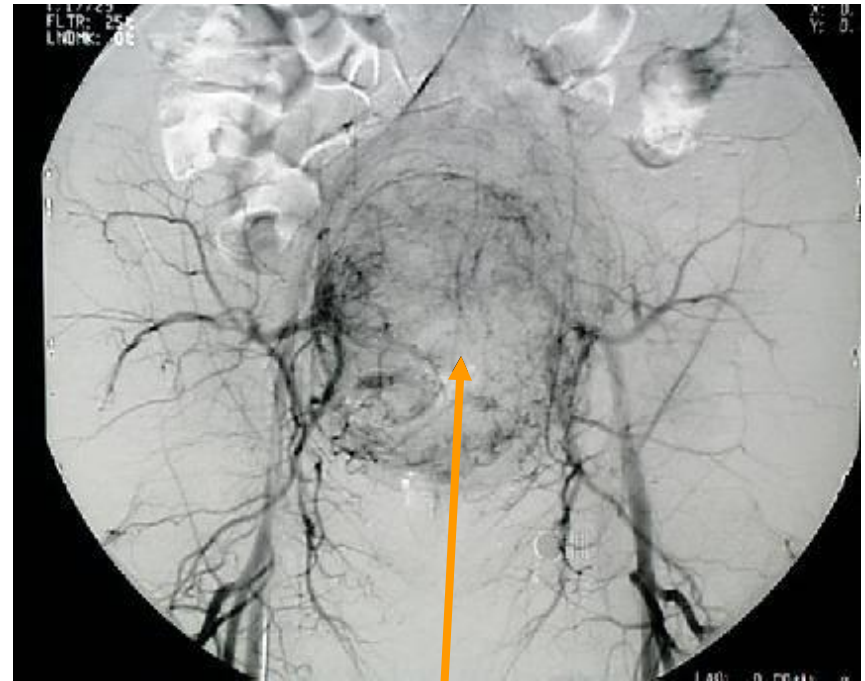
Angiographic Images of Fibroids

Pelvic angiogram

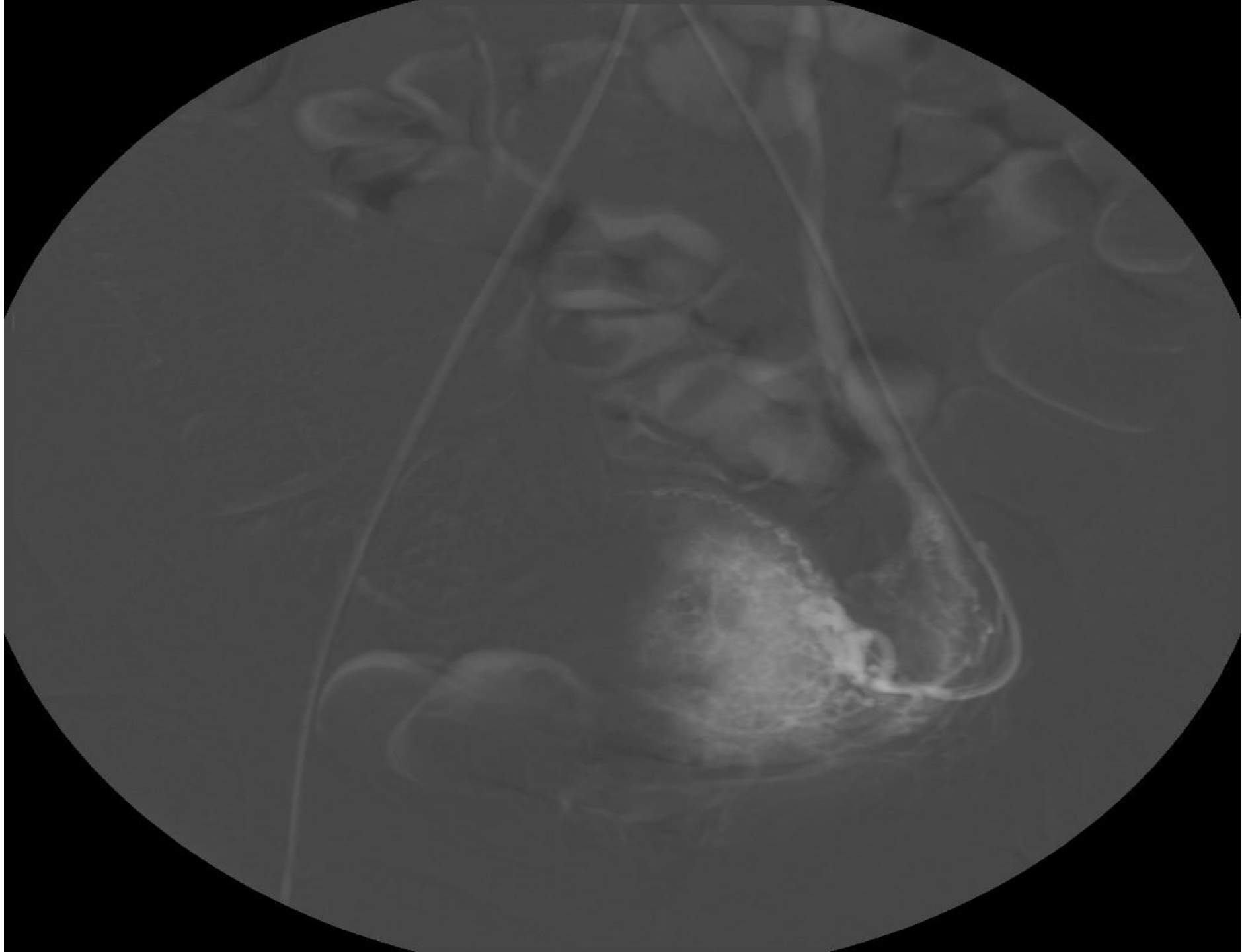


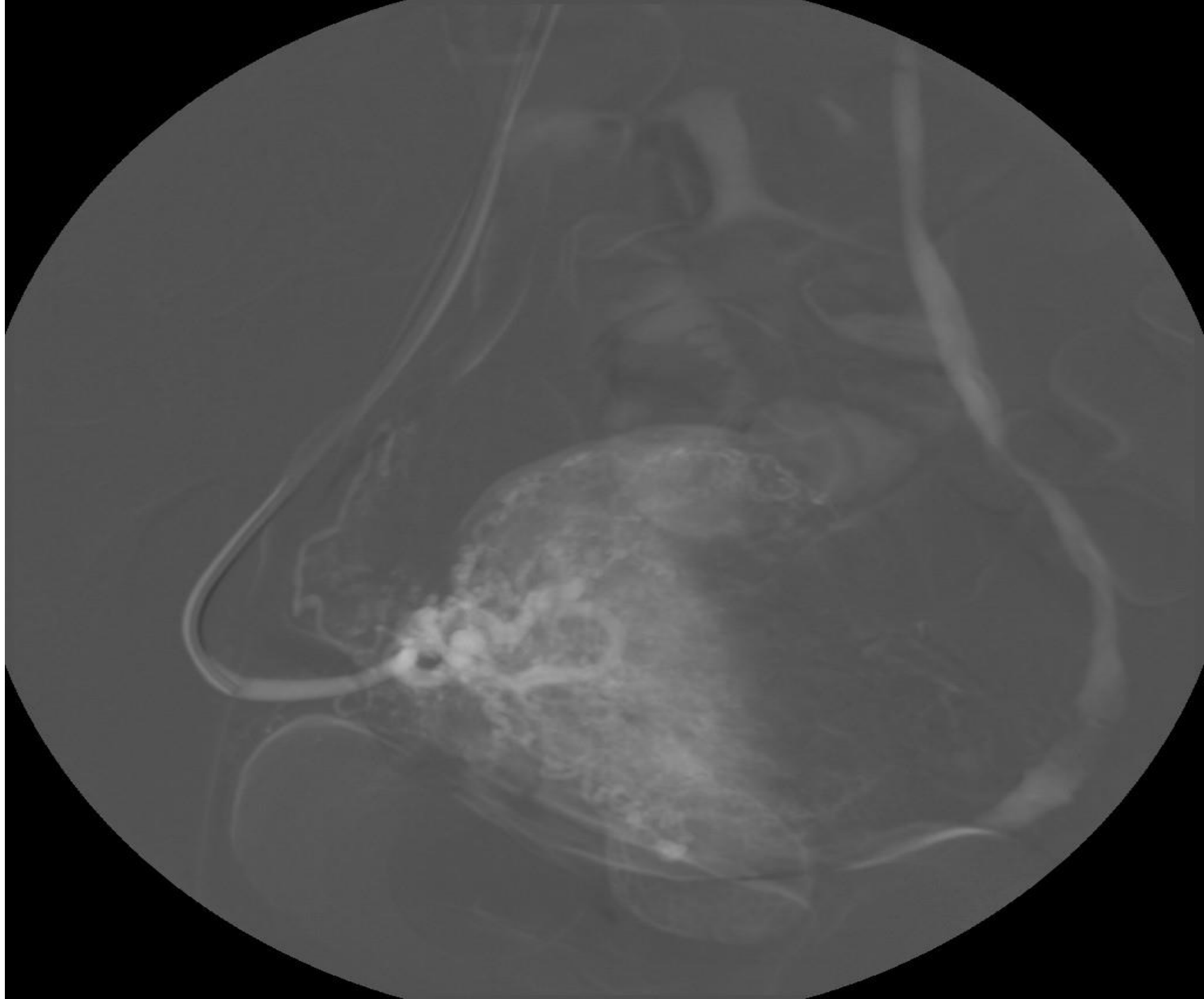
Uterus

Fibroid blood supply



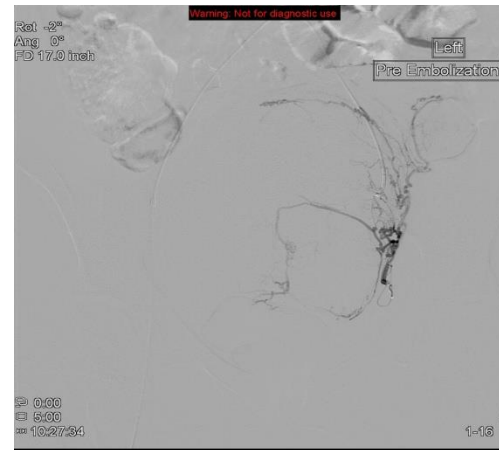
Fibroid





Targeted Uterine Fibroid Embolization

- Injection of microspheres continues until no hypervascular tumors are visible, pruned appearance in the feeder network, and slow flow in the uterine artery
- Stasis will be seen in the feeders
- Post-procedure image will show enhanced fibroids and normal myometrial perfusion



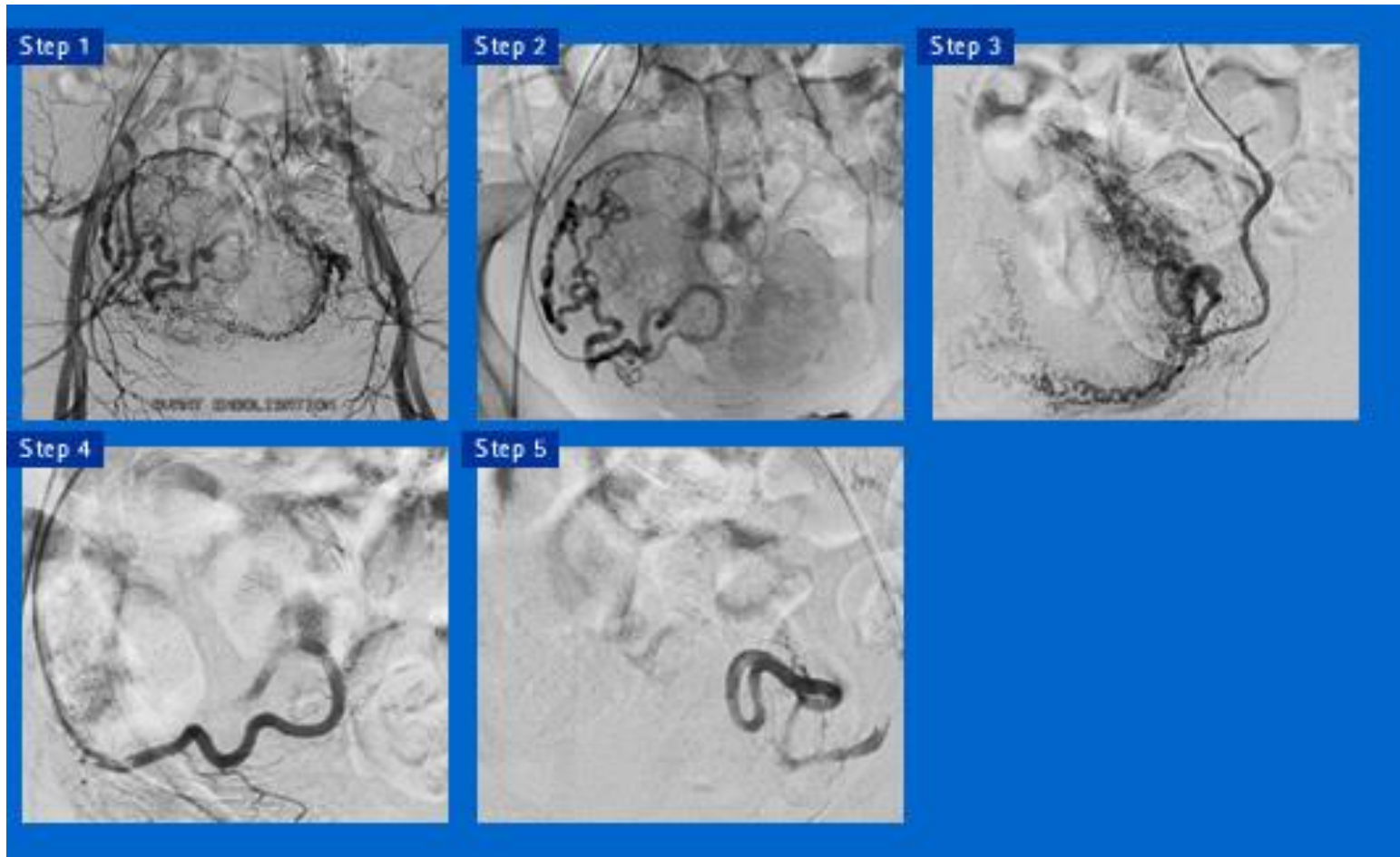
Pre-UFE

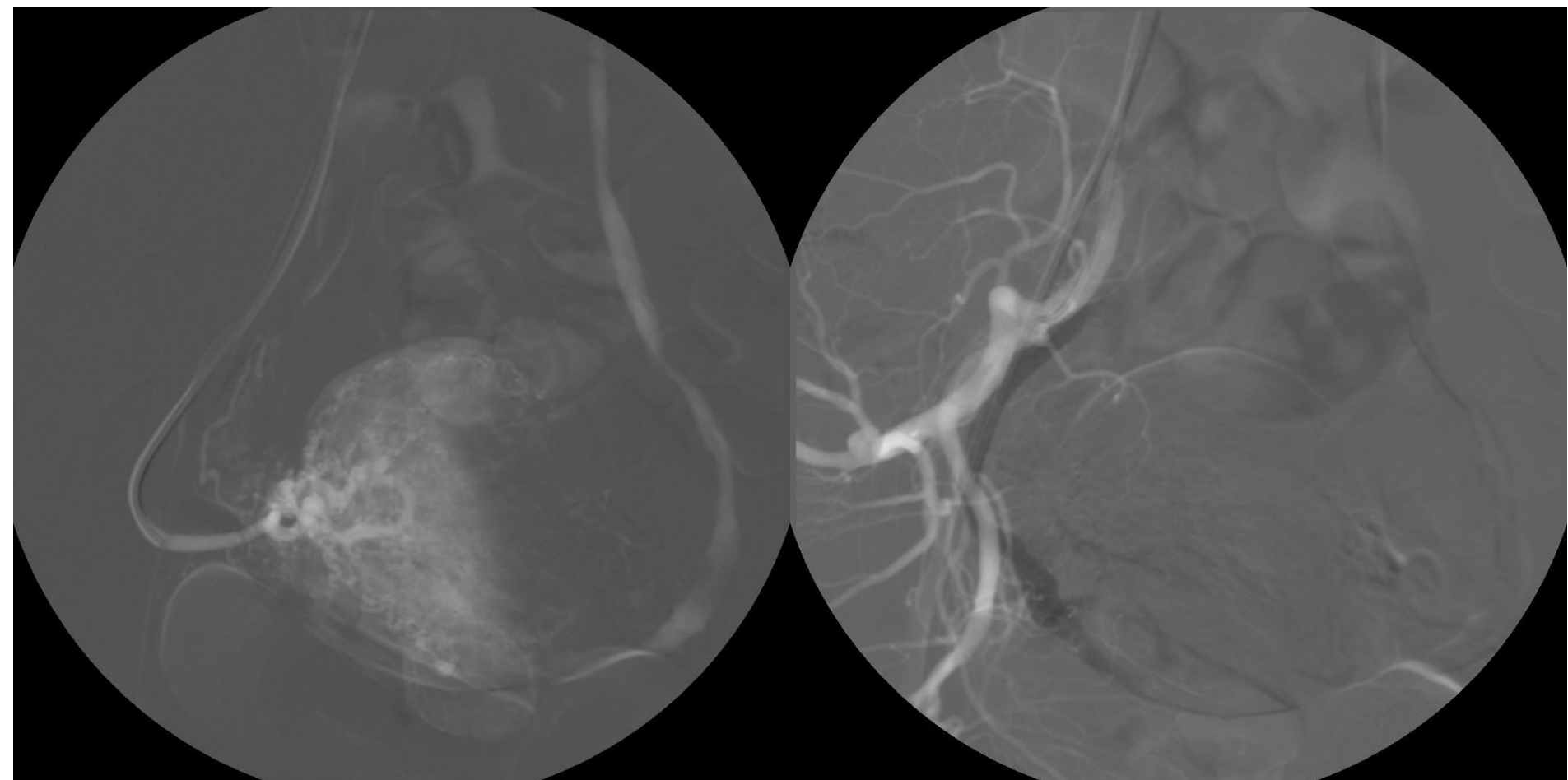


Post-UFE

Images courtesy Dr Jason R Levy.

Angiogram of Uterine Fibroids Before UFE (steps 1-3) and After UFE (steps 4-5)

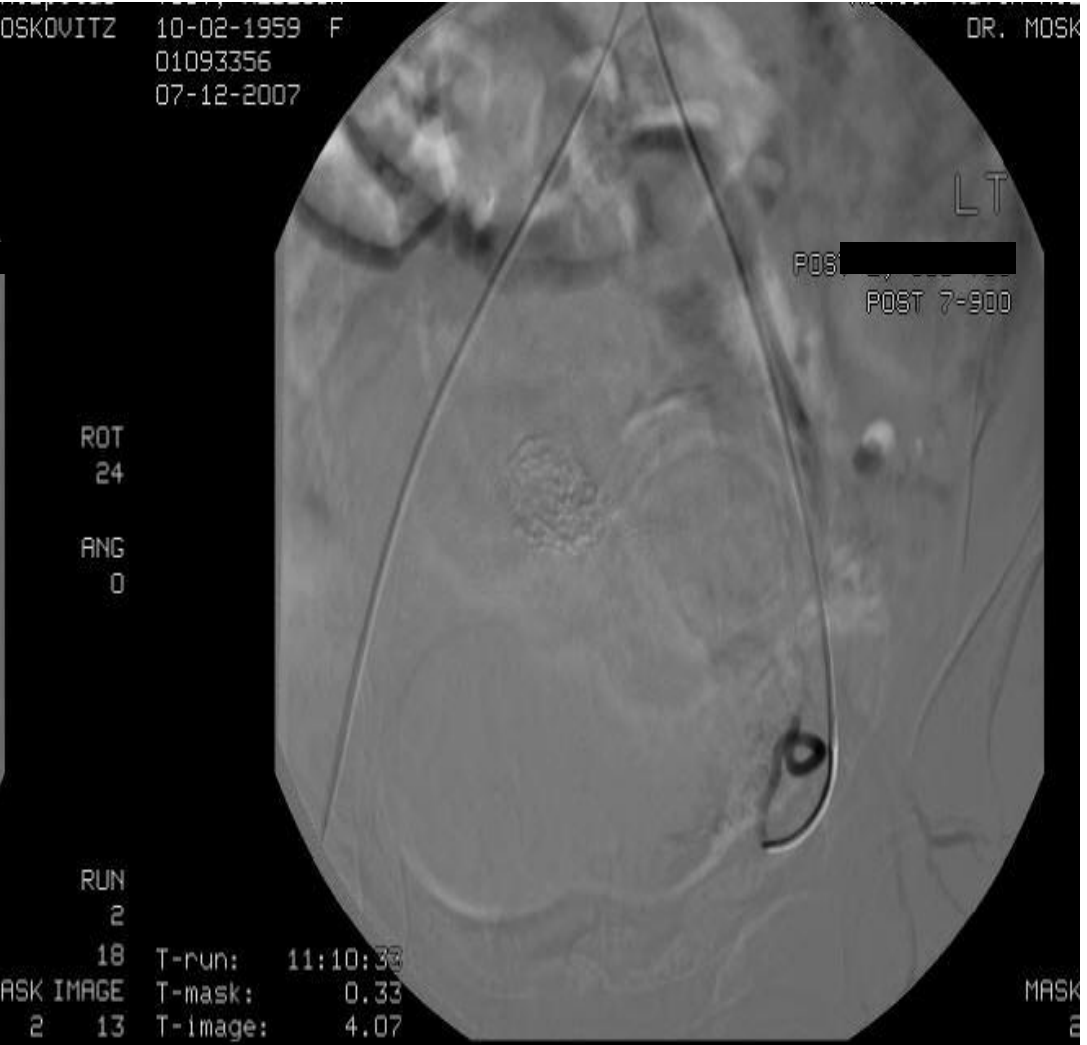
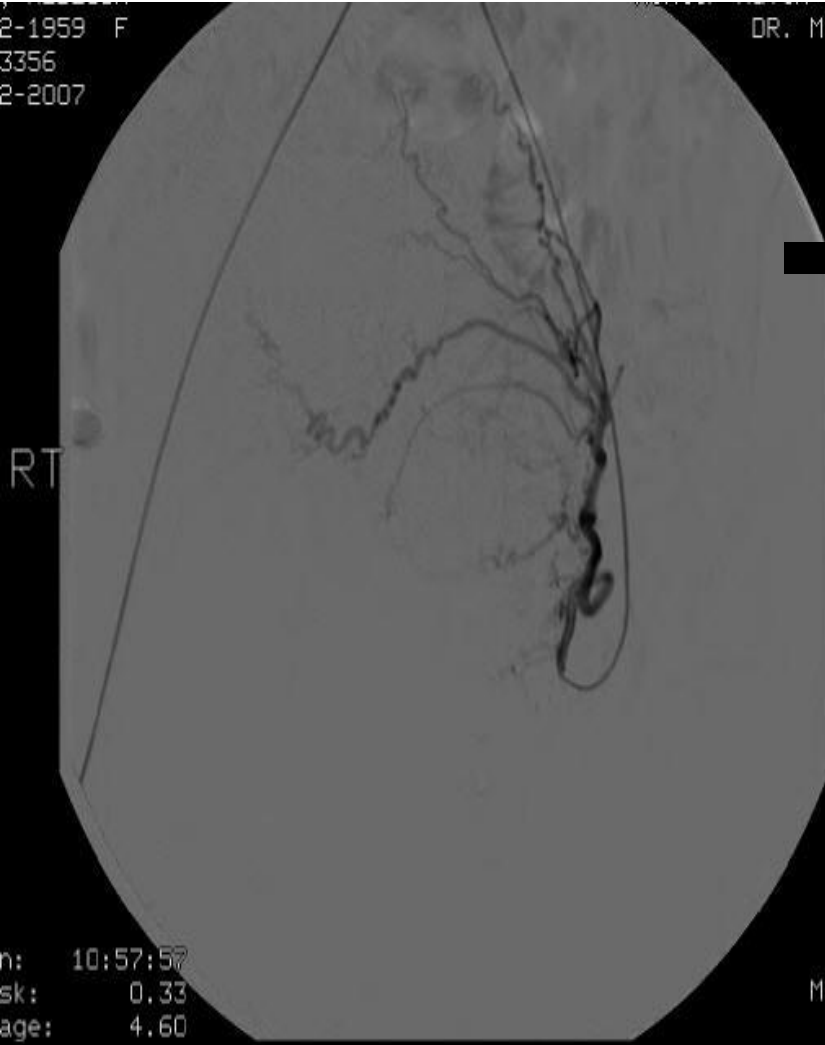




Before

After

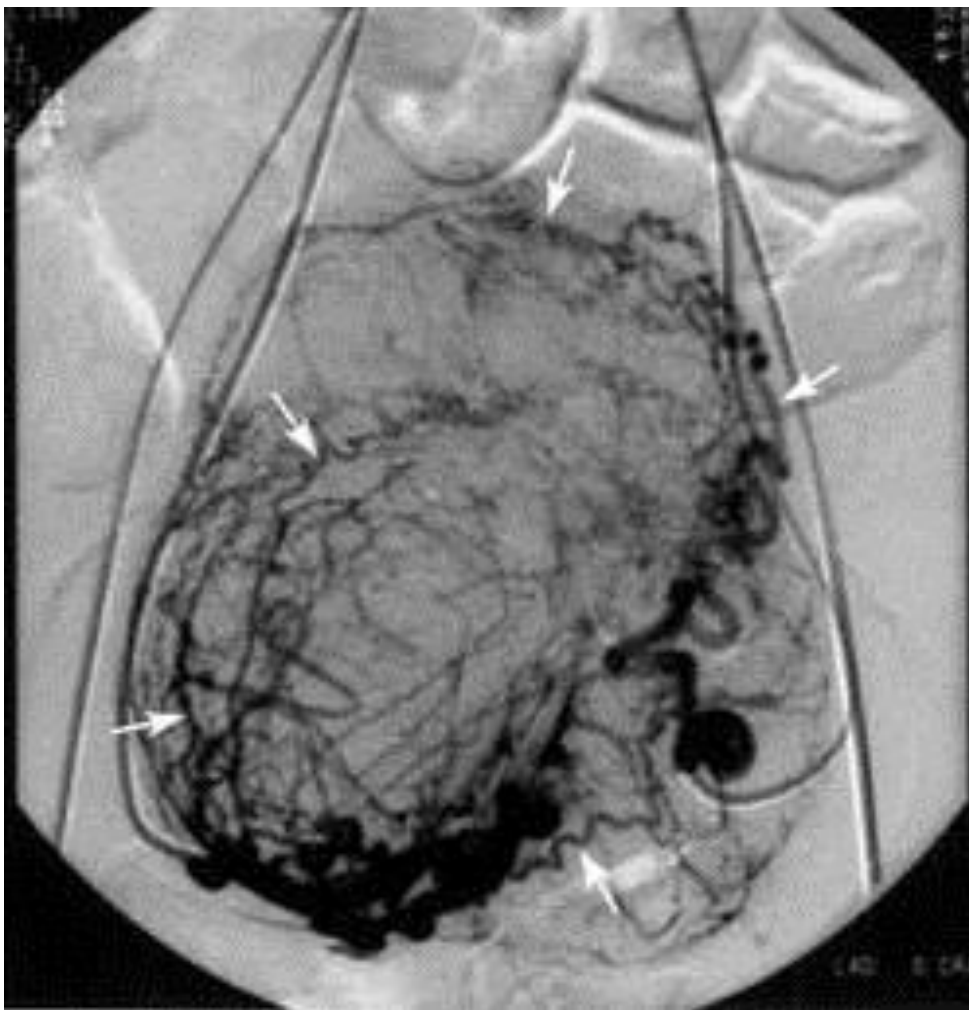
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Before

After

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Before

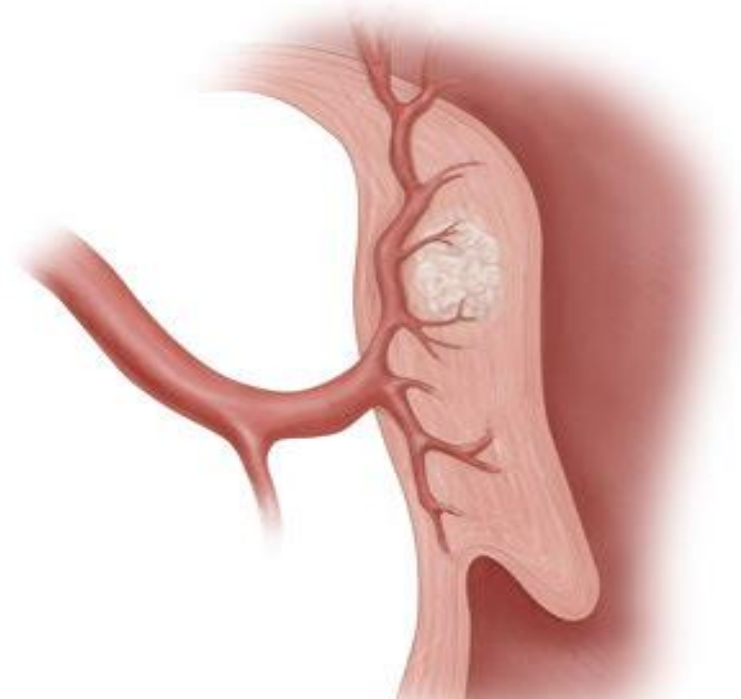


After

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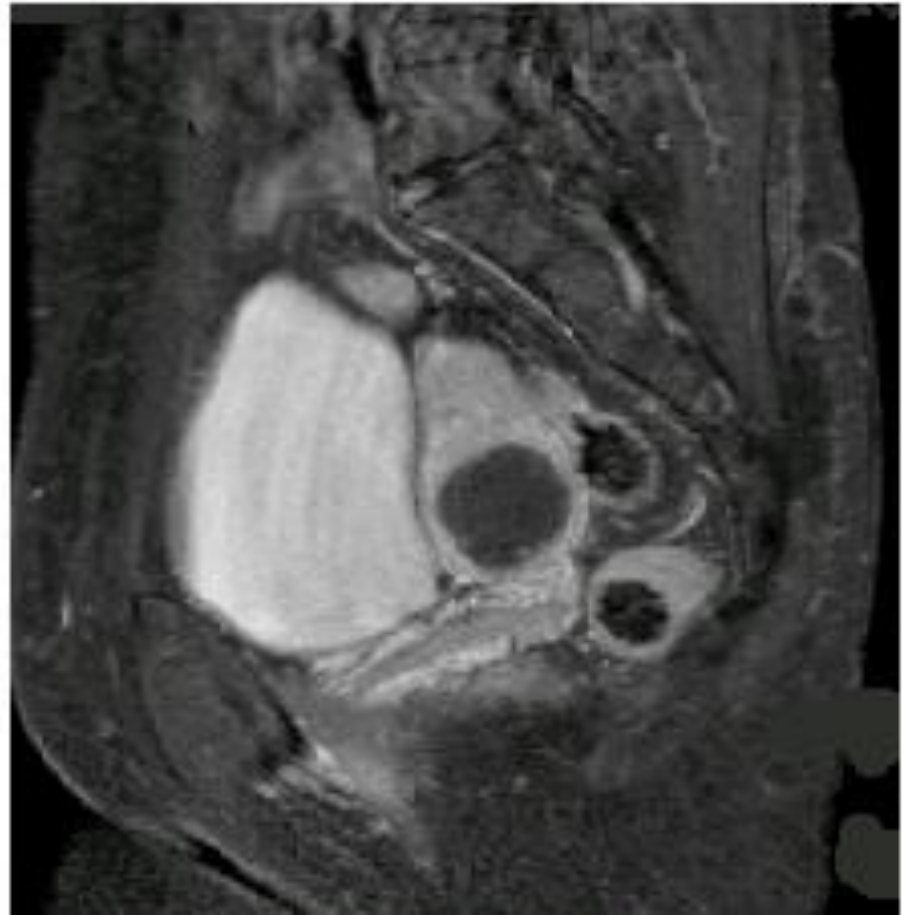
Uterine Artery Embolization

- Desired Results
 - Reduction in fibroid volume
 - Improvement in symptoms
 - Smaller and submucosal fibroids- more likely to have positive imaging outcome





Before



After

Uterine Artery Embolization Management

- Usually requires a hospital stay of one night
- Analgesics
 - Most women experience moderate to severe pain and cramping in the first several hours following the procedure
 - Acetaminophen- fever (occasional side effect)
- Resume light activities in a few days
- Majority of women return to normal activities in 1 week

Pain Management

- Combine anti-inflammatory medicines with narcotics
- ACUTE PHASE (First 24 hours)
 - Narcotics, NSAID & anti-emetics
 - Over 99% of patients are discharged within 23 hours and many institutions discharge on same day
- 1 to 8 days post UFE
 - Oral NSAIDs with opiates for breakthrough pain
 - Control of constipation is crucial to controlling pain
 - Patients are instructed to call the interventional radiologist for questions regarding the pain

Edwards RD, Moss JG, Lumsden MA, et al. Uterine artery embolization versus surgery for symptomatic uterine fibroids. The REST investigators. *N Engl J Med* 2007;356:360–370.

Siskin GP, Stainken BF, Dowling K, et al. Outpatient uterine artery embolization for symptomatic uterine fibroids: experience in 49 patients. *J Vasc Interv Radiol* 2000;11(3):305–311

UFE Complications Summary

Overall Complications	5%
Fibroid expulsion	2.5%
DVT	<1%
Recurrent/prolonged pain	1.3%
Transcervical fibroid expulsion	0-3%
Endometritis	.5%
Ovarian failure	
•Patient < 45 years	<1%
•Patient > 45 years	7-14%
Groin site complications	.25%

“Complications After Uterine Artery Embolization for Leiomyomas,” Spies JB et al; *Obstetrics & Gynecology*, Vol. 100, No. 5, Part 1, November 2002.

“Standards of Practice:Quality Improvement Guidelines for Uterine Artery Embolization for Symptomatic Leiomyomata.” Hovsepian et al; *J Vasc Int Rad* 2004; 15:535-542.

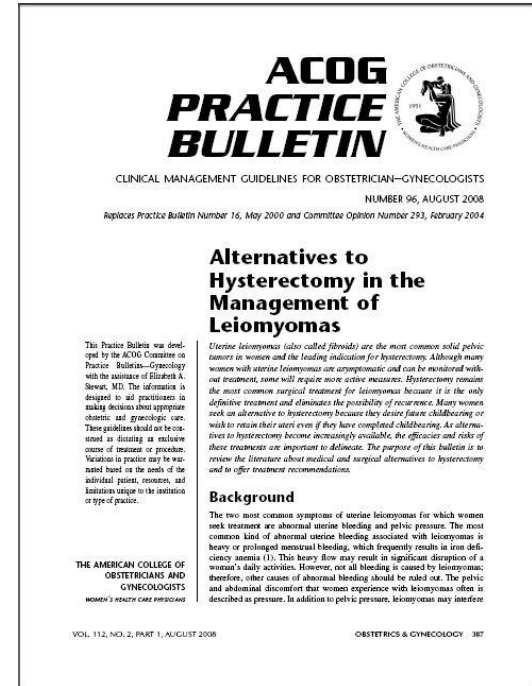
The Literature

ACOG 2008 Practice Bulletin

Alternatives to hysterectomy in management of leiomyomas

“Based on long and short-term outcomes, uterine artery embolization is a safe and effective option for appropriately selected women who would like to retain their uteri”

Level A evidence:
good and consistent scientific evidence.



ACOG Practice Bulletin: Clinical management guidelines for obstetricians-gynecologists. Number 96, August 2008. *Obstet Gynecol* 2008;112:387-400.

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Outcome After UFE – 3 years after treatment

Study	N	Duration of follow-up	% with Symptom Control	Hysterectomy Rate	Recurrence Rate*
Spies et al <i>JVIR</i> 2007;18:203-07	96	36 months	> 80%	9.7%	11.1%
Katsumori T et al <i>AJR</i> 2006;186:848-854	96	37.4 months (mean)	89.5%	3%	10.5%
Broder MS, et al <i>Obstet Gynecol</i> 2002;100:864-8	59	36 months (minimum)	92%	12%	29%
Bucek et al <i>AJR</i> 2006;186:877-882	62	36 months (range 1-5 years)	60-89.5%	Not reported	Not reported

*Defined as recurrence of symptoms leading to the need for hysterectomy, myomectomy or repeat UAE greater than 12 months after treatment.

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Long-term Outcome – 5 years or more

Study	N	Duration of follow-up	% with Symptom Control	Hysterectomy Rate	Recurrence Rate*
Moss JG, et al <i>BJOG</i> 2011; online	157	60 months	68%	18%	Not reported
Lohle P, et al <i>JVIR</i> 2008;19:319-26	100	54 months (median)	90%	11%	23%
Spies J, et al <i>Obstet Gynecol</i> 2005;106:933-9	200	60 months (minimum)	73% of total	13.7%	20%
Walker W, et al <i>BJOG</i> 2006;113:464-468	172	60-72 months	> 80%	5%	16%
Gabriel-Cox et al <i>AJOG</i> 2007;196:588.e1-588.e6	562	58 months	80%	19.7%	Not reported

*Defined as recurrence of symptoms leading to the need for hysterectomy, myomectomy or repeat UAE greater than months after treatment.

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Myomectomy Recurrence Rates

Study	N	Duration of Follow-up	Hysterectomy Rate	Recurrence Rate
Finn et al <i>AJOG</i> 1950;60:109-116	274	4-8 years	9%+	23%
Brown et al <i>AJOG</i> 1967;99:126-129	95	5+ years	32%	
Malone LJ, et al <i>Obstet Gynecol</i> 1969;34:200-203	125	5+ years	Single: 11% Multiple: 26%	Single: 27% Multiple: 59%
Candiani, et al <i>BJOG</i> 1991;98:385-389	622	10 years cumulative		27%
Acien et al <i>Fert Steril</i> 1996;65: 41-51	80	10 years cumulative	18%	38%

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UFE Benefits Compared to Surgery

	UFE ^(a)	Hysterectomy ^(a)	Myomectomy ^(b)
Hospital stay	< 1 day	2.3 days	2.5 days
Return to work	10.7 days	32.5 days	37 days
Major complications^(c,d,e)	3.9% ^(a) 4.0% ^(b)	12%	5.4-25%

- a) Spies, J.B., et al. (March 2004). Outcome of uterine embolization and hysterectomy for leiomyomas: Results of a multicenter study. *American Journal of Obstetrics and Gynecology*, 191, 22-31.
- b) Goodwin, S.C., et al. (January 2006). Uterine artery embolization versus myomectomy: a multicenter comparative study. *Fertility and Sterility*, 85, 14-21.
- c) Spies, J.B., et al. (November 2002). Complication After Uterine Artery Embolization for Leiomyomas. *Obstetrics and Gynecology*, 100, 873-880.
- d) Subramanian S et al. (October 2001). Outcome and resource use associated with myomectomy. *Obstet Gynecoll*, 98(4):583-7.
- e) Razavi et al. (June 2003). Abdominal Myomectomy Versus Uterine Fibroid Embolization in the Treatment of Symptomatic Uterine Leiomyomas. *AJR*:180, 1571-5.

Literature Search

- 23 articles from randomized studies
- 13 articles results of comparison to other therapies
 - REST Trial (UFE vs Surgery, primarily hysterectomy)
 - Emmy Trial (UFE vs Hysterectomy) (8 articles)
 - Pinto Trial (UFE vs Hysterectomy)
 - Mara Trial (UFE vs Myomectomy)(2 articles)
 - Hald Trial (Lap. UA occlusion vs UFE)

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Uterine Fibroid Embolization – Conclusions from Randomized studies

- Randomized studies show uterine embolization similar in outcome for symptom control compared to surgical alternatives
- Uterine embolization has a faster recovery for most patients than surgery
- Very few major complications.
- It appears that for 80 to 90% of patients, UFE provides excellent symptom control for up to 3 years and beyond

*REST Investigators. Uterine artery embolization versus surgery for symptomatic uterine fibroids. *NEJM* 2007; 356: 360-370.

*Mara M et al, Uterine fibroid embolization versus myomectomy in women wishing to preserve fertility: preliminary result of a randomized controlled trial. *Eur. J Obstet Gynecol and Reprod Biol* 2006; 126:226-223.

*Hehenkamp WJK, et al. Symptomatic uterine fibroids: treat with uterine artery embolization or hysterectomy--results from the randomized clinical Embolisation versus Hysterectomy (EMMY) Trial. *Radiology* 2008;246:832-32

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Uterine Fibroid Embolization – Literature Conclusions on Fertility

- Results on UFE on fertility are preliminary and uncertain
- Initial reproductive results appear to favor myomectomy over embolization in first 2 years after treatment
- Additional studies comparing the impacts of myomectomy and embolization on ovarian function and to better assess reproductive outcomes are needed
- One recent retrospective study demonstrated pregnancy rates on par with post myomectomy studies and no increase in pregnancy related complications
- ^{*} Case reports have been published of successful deliveries after UFE

Pisco. Pregnancy after Uterine Fibroid Embolization. *Fertil Steril*. Article in press

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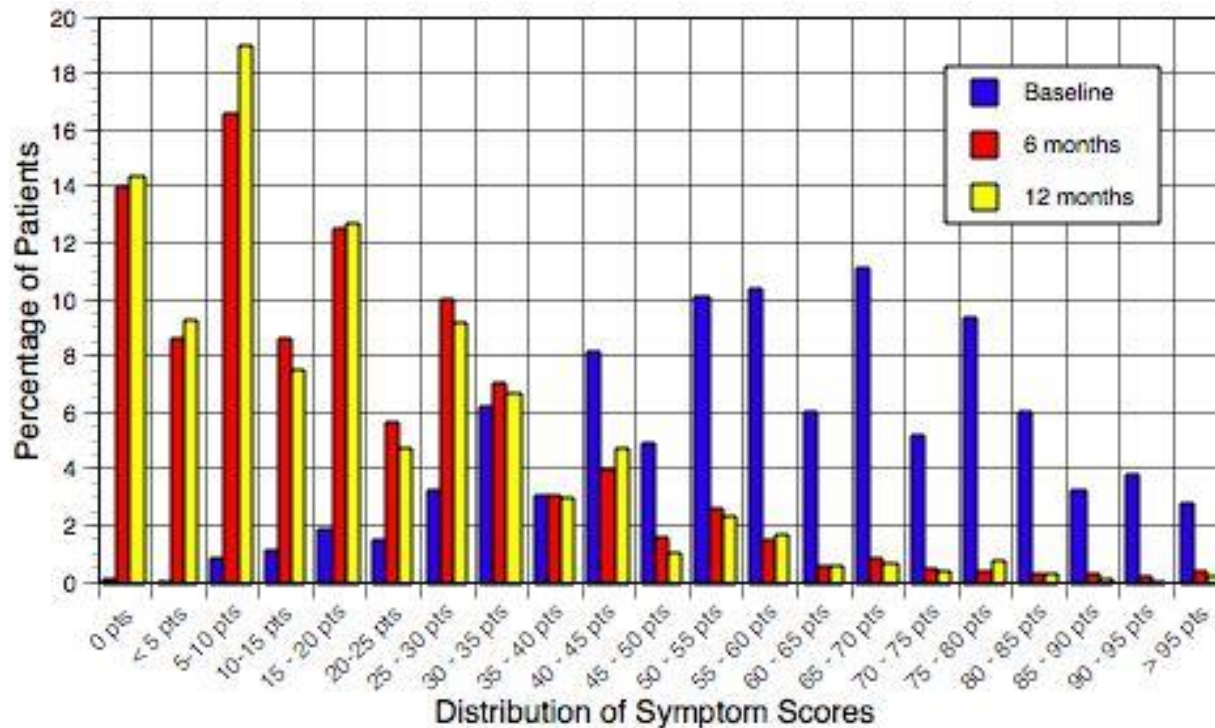
The FIBROID Registry – Enrollment

- Fibroid Registry for Outcomes Data (FIBROID)
- Purpose: to collect prospective data on a large number of women undergoing uterine artery embolization
- Largest registry of any female pelvic procedure
- Published in *Obstetrics & Gynecology* (4 articles)
 - Initially, 3319 patients treated at 72 enrolling sites
 - 3166 (95.4%) consented to Registry
 - Complete variables in 3005 (94.9%)
 - Thirty-day follow-up complete in 2729 (90%)
 - 2112 eligible for long-term follow-up
 - Six month follow-up completed in 1797 (85.1%)
 - Twelve month follow-up completed in 1701 (83%)
 - Three year follow up survey completed in 1278

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FIBROID Registry Symptom Scores

	Baseline N = 2666	6 months N = 1797	12 months N = 1701	Normal population score
Symptom Score Mean (S.D.)	59.83 (20.8)	19.87 (18.6)	19.23 (17.9)	22.5 (21.1)

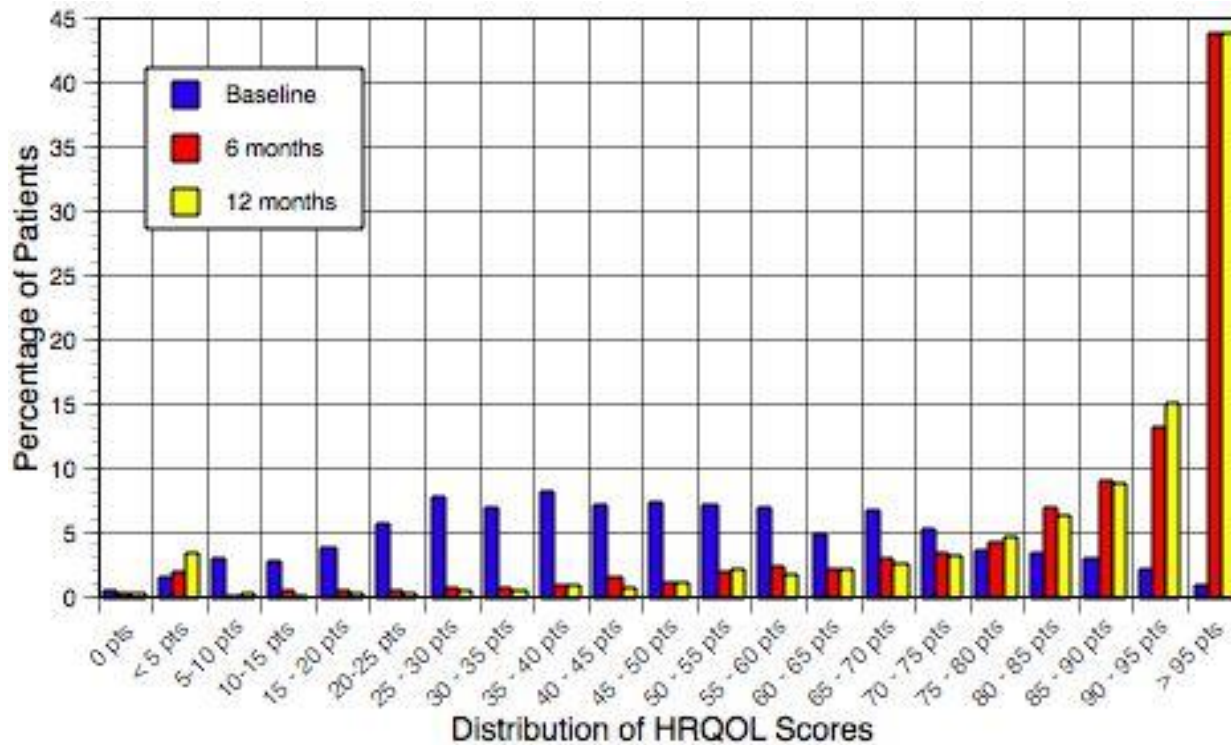


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FIBROID Registry Quality of Life Scores

	Baseline N = 2666	6 months N = 1797	12 months N = 1701	Normal population score
HRQOL Score Mean (S.D.)	47.32 (22.9)	85.0 (20.1)	86.7 (18.1)	86.4 (17.7)



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UFE Long-term Outcome* – Summary of Results

N (%**)	3 M	1 Y	2 Y	3 Y	4 Y	5 Y
Symptoms						
Improved	180 (93)	166 (87)	136 (85)	152 (83)	143 (79)	133 (73)
Not Improved	9 (5)	10 (5)	8 (5)	7 (4)	6 (3)	10 (5)
Failed	4 (2)	14 (7)	17 (11)	25 (14)	30 (17)	36 (20)
Expired	0 (0)	0(0)	0 (0)	0 (0)	2 (1)	3 (2)
Missing	7	10	39	17	20	18

85-90% said they would recommend UFE to
a friend or relative*

*Spies JB, et al. Long-Term Outcome of Uterine Artery Embolization of Leiomyomas. Obstet Gynecol 2005;106:933-9.

** Percent of known values, rounded to nearest whole number. All patients followed 5 years.

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Patient Selection

UFE Indications

“UFE is indicated for individuals with clinically documented fibroids and fibroid-related symptoms who wish to avoid surgery.”

Bradley. Uterine fibroid embolization: a viable alternative to hysterectomy. *Am J Obstet Gynecol* 2009.

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Ideal Candidates for UFE

- **Most patients with symptomatic fibroids**
- Patients with symptomatic fibroids and not pregnant
- Patients wishing to avoid surgery and/or long recovery
- Patients desiring uterine preservation
- Perimenopausal patients
- Poor surgical candidates
 - Medical: anemia, anti-coagulated, obesity, cardiac disease, ...
 - Surgical: extensive adhesive disease
 - Refusing blood products
- Patients who do not desire future fertility
- Patients with hysterectomy/HRT concerns

Contraindications to UFE

Absolute

- Viable pregnancy
- Active pelvic infection
- Undiagnosed pelvic mass
- Genital tract malignancy
- Arteriovenous shunting

Relative

- Submucosal
Pedunculated fibroids
- Severe Contrast allergy
- Renal insufficiency
- Adenomyosis
- Desire for future fertility

“Role of Magnetic Resonance Imaging in Patient Selection for Uterine Artery Embolization; Cura M et al; *Acta Radiologica* 2006 (10).

Working with Interventional Radiology

Collaboration Leads to Optimal Patient Care



ELSEVIER

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Original Article

The Effect of a Gynecologist–Interventional Radiologist Relationship on Selection of Treatment Modality for the Patient with Uterine Myoma

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From the Department of Obstetrics and Gynecology (Dr. Zurawin) and St. Luke's Episcopal Hospital (Dr. Fischer), Baylor College of Medicine, Houston, Texas, and the Institute for Quality Resource Management, VantageView LLC (Dr. Amir), St. Louis, Missouri.

Conclusions: Establishing a referral relationship with an interventional radiologist for comprehensive uterine myoma treatment supports a trusting, collaborative, long-term, noncompetitive “win-win” relationship between the gynecologist and radiologist, meets the patient’s desire for full disclosure of all myoma treatment options, improves the patient’s overall medical care and physician/patient experience, and has been demonstrated to improve patient flow to a gynecologist practice. With the guidelines established in this study, no patients were inappropriately left to the gynecologist for post-UAE care. The authors acknowledge that this dynamic is dependent on the individual interventional radiologist and their relationships and open communication with the gynecologist. Finally, the study revealed that failure to fully disclose alternative treatment options, or offer minimally invasive surgical techniques may result in a loss of patients due to patient dissatisfaction. *Journal of Minimally Invasive Gynecology* (2010) 17, 214–221 © 2010 AAGL. All rights reserved.

All fibroid patients have two referral pathways to best inform their treatment decision



IR
for minimally invasive,
non-surgical options

Ob/Gyn
for surgical options

Patients who are not UFE candidates are referred to Gyn for surgical options



Understanding What to Expect When Referring to an Interventional Radiologist Who Provides Optimal Care

Pre-procedure, the IR will:

- Provide patient education and answer questions regarding UFE procedure
- Initiate pre-UFE consult with patient and coordinate workup with referring physician
- Communicate to referring physician if she is a candidate, and coordinate scheduling of the procedure
- Arrange any additional studies that are necessary pre-procedure
- Admit patient into hospital and perform procedure

Post- procedure, the IR will:

- Manage the catheter site care
- Admit for overnight stay
- Provide for 24/7/365 pain & complication management
- Explain discharge instructions/meds to the patient
- Schedule patient follow up visits
- Provide complete patient follow-up care and communicate key issues/procedure results with referring physician

UFE Summary

- UFE is proven effective with durable symptom control
- >150,000 UFE procedures worldwide
 - 30,000 procedures performed per year in the United States
- 80-95% clinical success
 - bleeding and bulk-related symptoms
- Clinical studies show equivalent symptom relief as compared to surgery
 - with less recovery time and complications
- Minimally invasive
 - < 23 hour hospital stay for most
- Return to normal activity in about 1 week
- Low complication rate

Resources

- www.ask4ufe.com physician locator
- www.sirweb.org physician locator
- www.omniaeducation.com online CME
- Patient brochures

Questions & Answers