

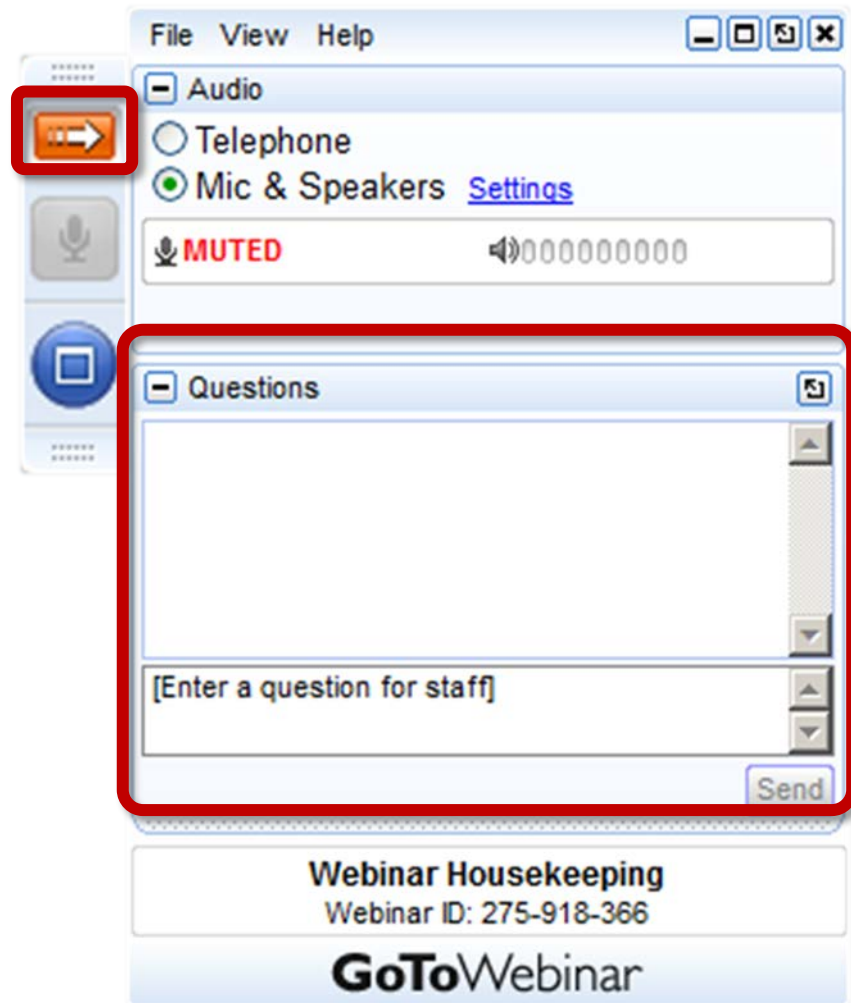


# Understanding the UFE Experience in an Outpatient Setting



MURAT H. SOR, MD ■ T. CADE RAGGIO, MD  
HealthQare Associates  
QUALITY DOCTORS, QUALITY CARE

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# HealthQare Associates

## Quick Facts:



Fresenius Vascular Care

Location: Arlington, VA

Medical Director: **Murat Sor, MD**

Hours of operation: Monday-Friday 7:30am-5:00 pm

Services we provide: Dialysis Access Management,  
Treatment of Pelvic Congestion, Peripheral Artery Disease (PAD),  
Varicose Veins, Varicoceles



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# Cade Raggio, MD

## Interventional Radiologist

### **EDUCATION**

Stanford University

Louisiana State University School of Medicine

### **RESIDENCY & FELLOWSHIP**

Georgetown University Hospital

### **SOCIETAL MEMBERSHIPS**

Society of Interventional Radiology

American College of Radiology

American Medical Association

# Agenda

- The UFE\* Procedure in an Outpatient Setting
- Patient Selection
- Pain Management
- Clinical Outcomes in Recent Literature
- Q&A
- Conclusion

\*UAE and UFE used interchangeably and are the same procedure

# The UFE Procedure in an Outpatient Setting

# Uterine Fibroid Embolization (UFE)

\* Also referred to as Uterine Artery Embolization (UAE)

Procedure approved by American College of Obstetrics & Gynecology  
Minimally invasive endovascular outpatient procedure

Low major complication rate

Lower rate of recurrence than myomectomy

Lower cost than surgery (cost could be offset by re-intervention)

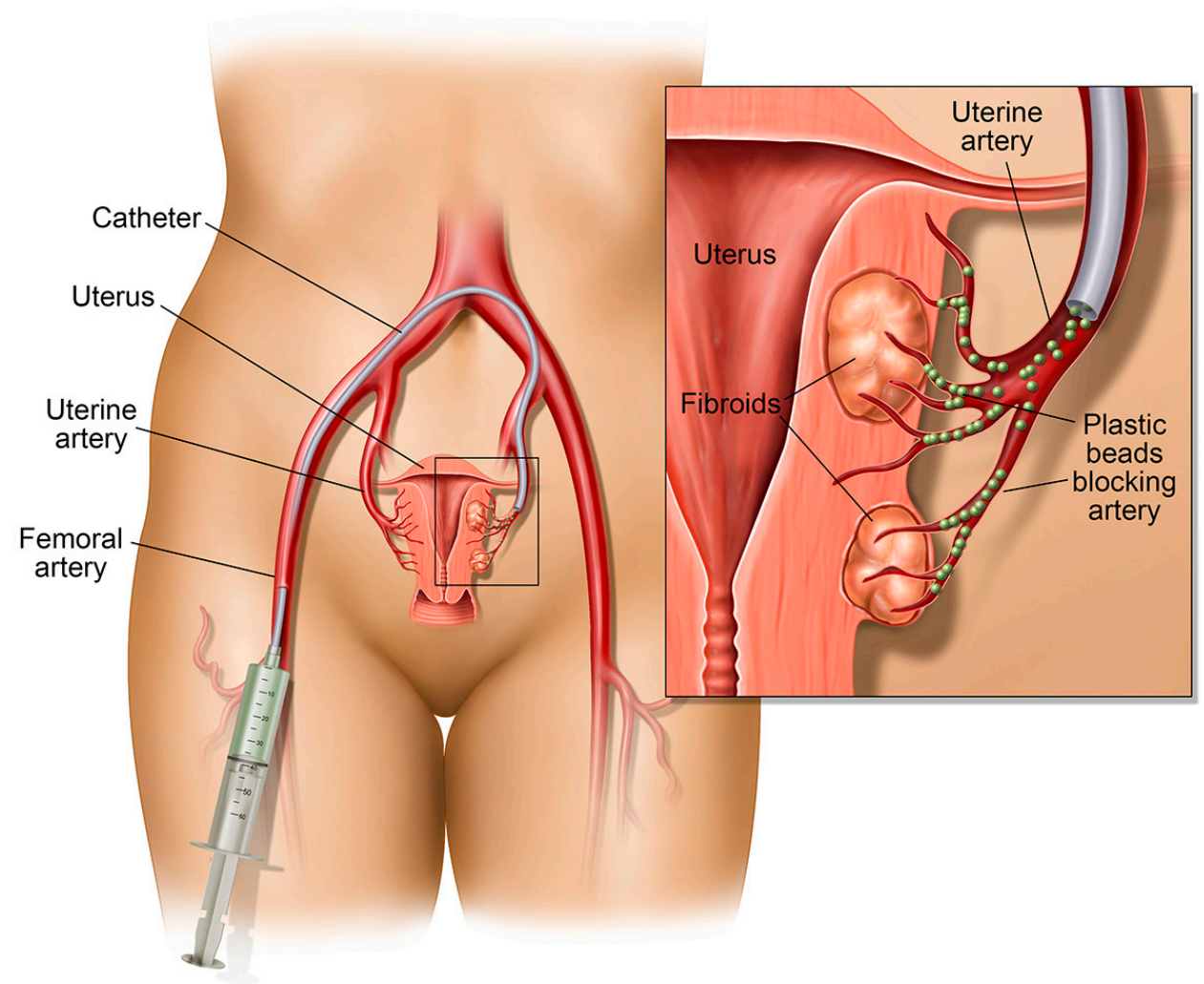
High patient satisfaction **> 90%**

Rapid return to work **3-10 days**

# UFE Procedure

## Unilateral or bilateral groin punctures w/5 Fr sheath

- + Unilateral: easier for single operator
- + Bilateral: lower radiation dose, faster procedure time





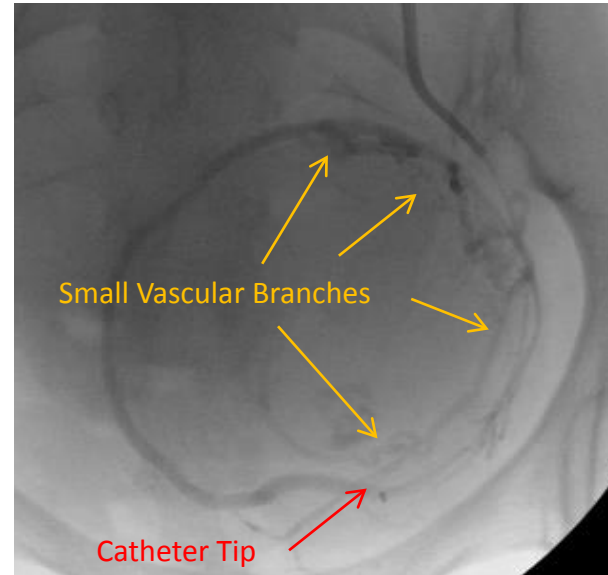
# UFE Procedure

The embolic agent is an inert particle.

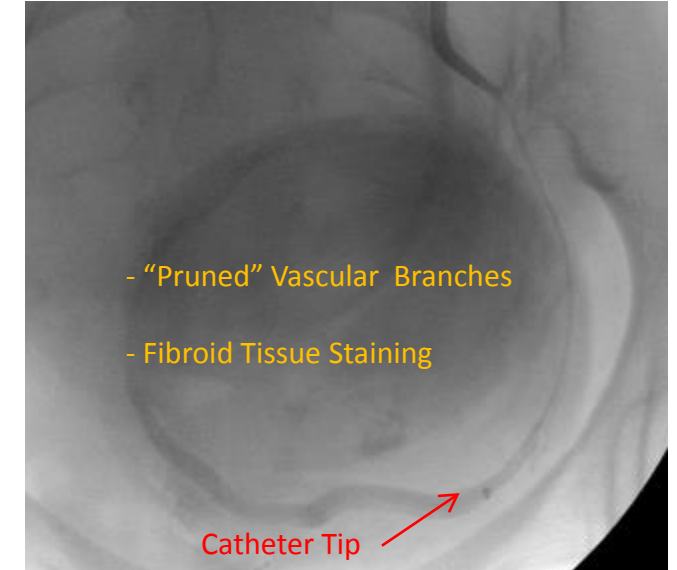
Embolic agent is delivered to each uterine artery.

Endpoint reached when there is no more “staining” of fibroid tissue.

Fibroids are hypervascular and more sensitive to ischemia than normal tissue.

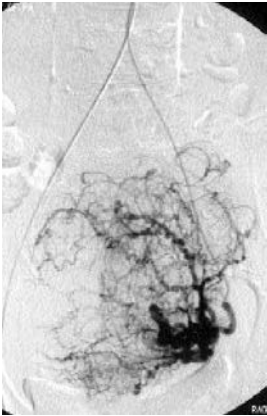


Pre-Embolization



Post-Embolization

# UFE Procedure



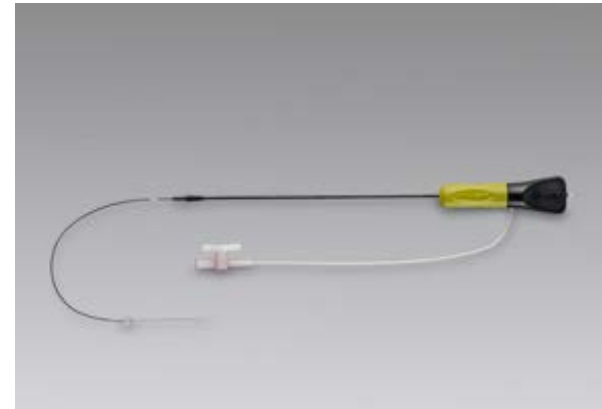
Roberts Uterine Catheter



Renegade™ HI-FLO™ Microcatheter



Embolization Particles



MYNXGRIP® Vascular Closure Device

# Post-Procedure

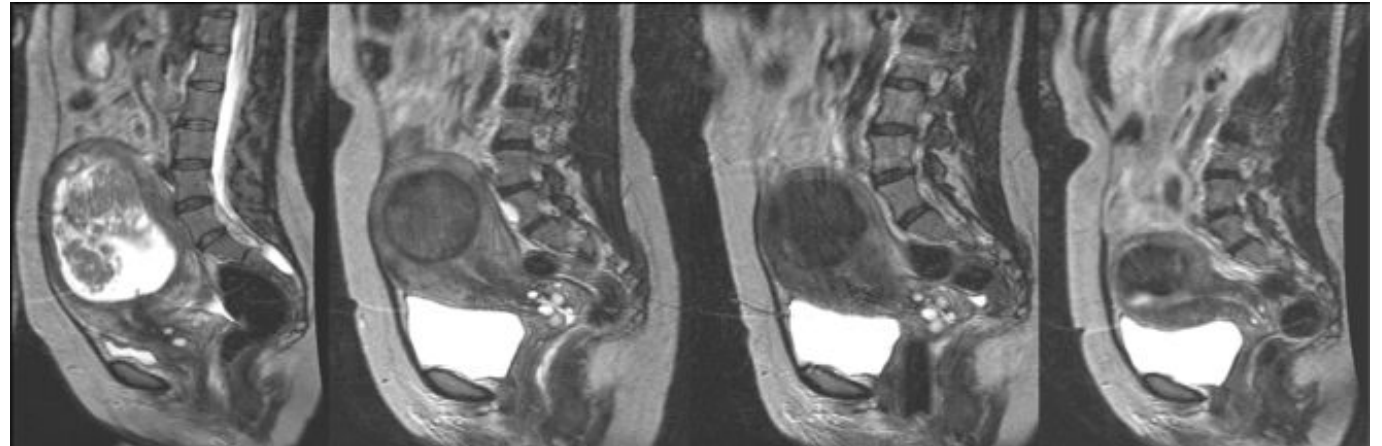
## Fibroids become ischemic

- Pain peaks within first 24 hours, then subsides

## Post-embolization Syndrome (PES)

- Low grade fever
- Fatigue/malaise
- Flu-like symptoms

Symptoms subside within 7-10 days



## Bloody discharge for up to 2 weeks

# Post-Procedure Management

## How We Manage Patients

Our patients are instructed to call any time with questions or complications

- On-call **24/7** with direct access to physician
- Privileges at GW, Howard, WHC

Follow-up visits scheduled within **1 week** and at **3-4 months**

MRI at 3 months, only if symptoms are not improved

\* Referring physicians are provided with a procedure report within **24-48 hours**



# Patient Selection

# Patient Selection

Many American women will develop fibroids

By age 50, 80% African Americans & 70% Caucasians  
~10% symptomatic

Predisposing factors:

African American

Family History

Age

Early Menarche

Obesity

Hormonal Influences



## The Ideal Candidate for UFE

Premenopausal with symptomatic fibroids

Patient with desires to avoid surgery (hysterectomy, myomectomy)

Co-morbidities that make general anesthesia risky

Discussion with patient if future pregnancy is desired

# Patient Selection

## How We Select & Screen UFE Patients

In-office consultation with patient

MRI pre-procedure preferred but not necessary

Rule out confounding diagnoses and/or malignancy

CBC, Chem 7, (INR not needed unless clinical history indicates)

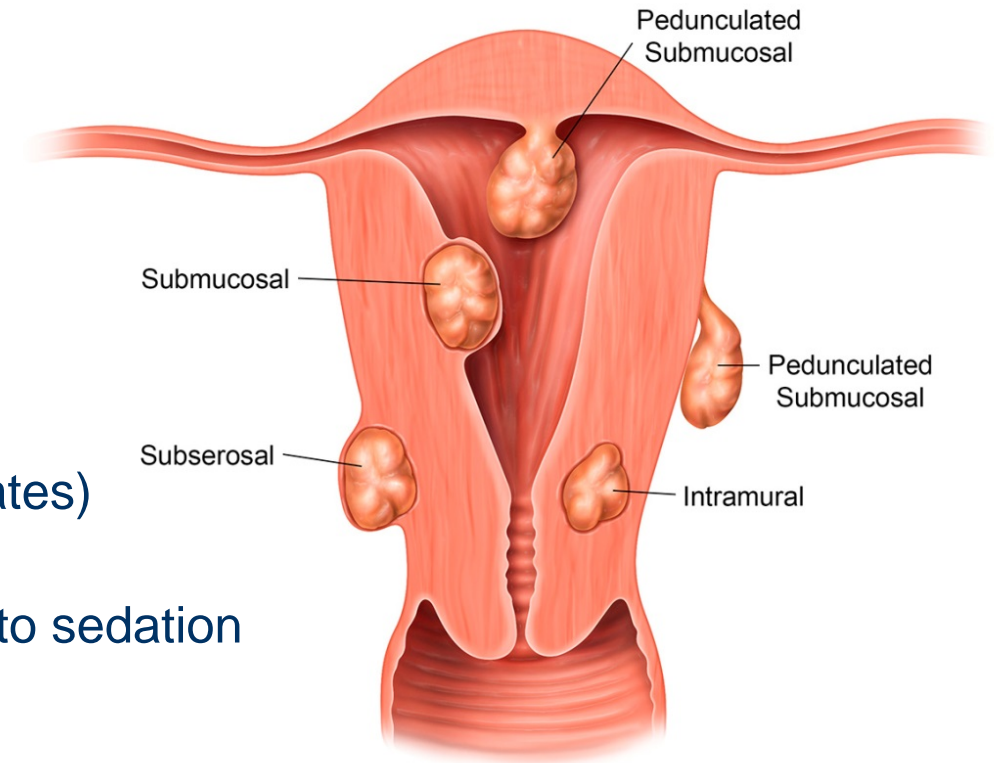
Inquire about history of contrast allergy or adverse reaction to sedation

Explore alternative treatment if desires future pregnancy

**All** fibroids can be effectively treated with UFE

Pedunculated, subserosal safe to treat

Caution: intra-cavitary or significant endometrial interface





# Patient Selection -- Adenomyosis

UFE is a safe and effective treatment for adenomyosis

Short term relief of symptoms in patients with pure adenomyosis **83-93%**

Long term symptomatic relief **65-82%**

- No level 1 data
- No comparisons of UAE to alternative treatments

# Patient Selection -- Pregnancy

## Data regarding pregnancy and UFE is generally low quality

UFE patients in these studies were older, +prior interventions, more extensive disease

INVESTIGATOR	OUTCOMES
Goldberg et. al.	Higher preterm labor, malpresentation vs. myomectomy
Homer and Saridogan	Higher miscarriage but not malpresentation or preterm labor
Mohan et. al.	Higher miscarriage vs. untreated but no difference in other complications
Pisco et. al.	60% pregnancy rate, lower complications vs other studies (young pts)
McLucas	48% pregnancy rate (similar to myomectomy). No IUGR reported.
Mara et. al.	Prospective, fertility outcomes favored myomectomy 11% technical failure for UFE (VERY high), crossover of patients limits study

# Patient Selection – Special Considerations

## High Risk for DVT

- If patient on Warfarin, consult with hematologist and/or PCP
  - Lovenox<sup>®</sup> pre-procedure, bridge to Warfarin until therapeutic
- Compression stockings
- Encourage ambulation post procedure
- In-office studies if suspicious of DVT

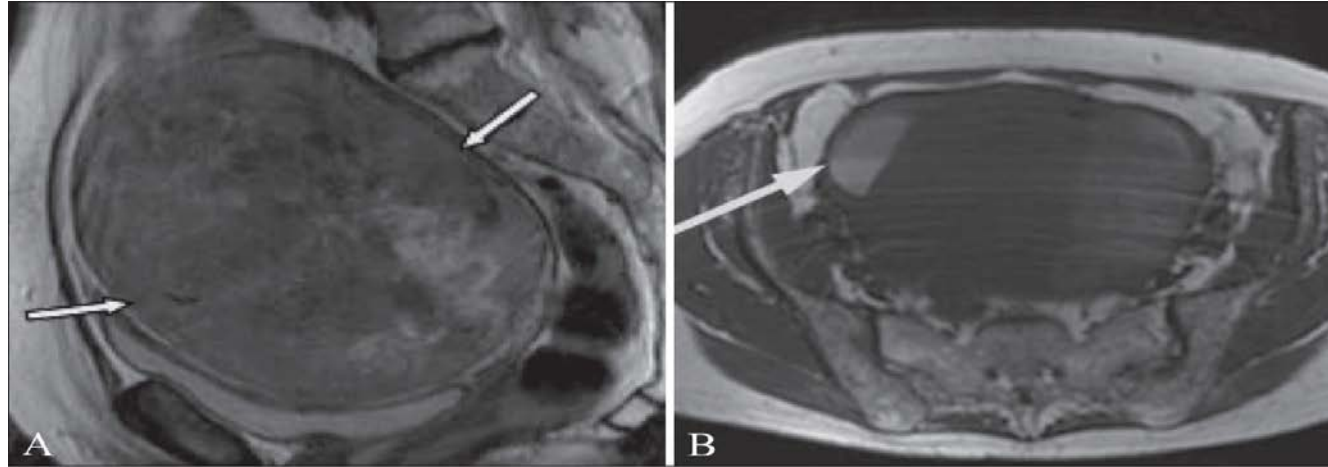
## IUD

- Consider removing prior to procedure
- Administer antibiotics peri-procedure (no strong data for this)

# Patient Selection – Special Considerations

## Uterine Malignancies

Estimate of leiomyosarcoma 1:250 – 1:8000



Recent clinical data:

- 21 of 866 patients (2.4%) MRI suspicious

  - 17 of 21 had complete op and path reports

  - 5 with MRI highly suspicious

  - 3 malignancy, 2 benign

  - 1 malignancy not detected by MRI (poor quality, open MRI)

MRI findings: heterogeneous, infiltrating, early enhancement

Diffusion not routinely done, but can be very helpful

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# Pain Management

# Pain Management

## Intra-procedure

Fentanyl/Midazolam/Propofol

Toradol® 30 mg IV  
(inflammation)

Dexamethasone 10 mg IV  
(inflammation and nausea)

Intra-arterial lidocaine

## Immediately Post-procedure

Fentanyl patch 25 mcg  
Q 72 hours

Dilaudid® 0.5 mg IV PRN

Zofran® 4 mg IV once,  
then PRN

## After Discharge

Dilaudid® 2 mg  
Q 4-6 hours PRN

NSAID (Naproxen 500 mg)  
BID x 10 days

Promethazine 12.5 mg PO PRN  
(prescription given for PR)

Colace®/Lactulose

# Clinical Outcomes

# Clinical Outcomes

**TABLE 6: Rates of Symptomatic Improvement**

Symptom	Follow-Up Duration (y)	No. of Patients Available <sup>a</sup>	Pooled Improvement Rate (%) (95% CI)
Menorrhagia	< 1	1434 (16)	87.5 (84.7–90.0)
	1–2	911 (13)	90.1 (85.8–93.7)
Bulk symptoms	< 1	945 (13)	86.6 (82.2–90.5)
	1–2	599 (9)	82.0 (75.4–87.7)
Dysmenorrhea	< 1	511 (7)	77.5 (73.8–80.9)
	1–2	549 (7)	84.4 (78.2–89.7)

**95%**

QOL improved significantly

**83-92%**

Sustained improvement in bleeding

**77-84%**

Reduction in pain symptoms (64% with no pain)

**79-92%**

Improvement in bulk related symptoms

**42-83%**

Fibroid volume reduction

**91-97%**

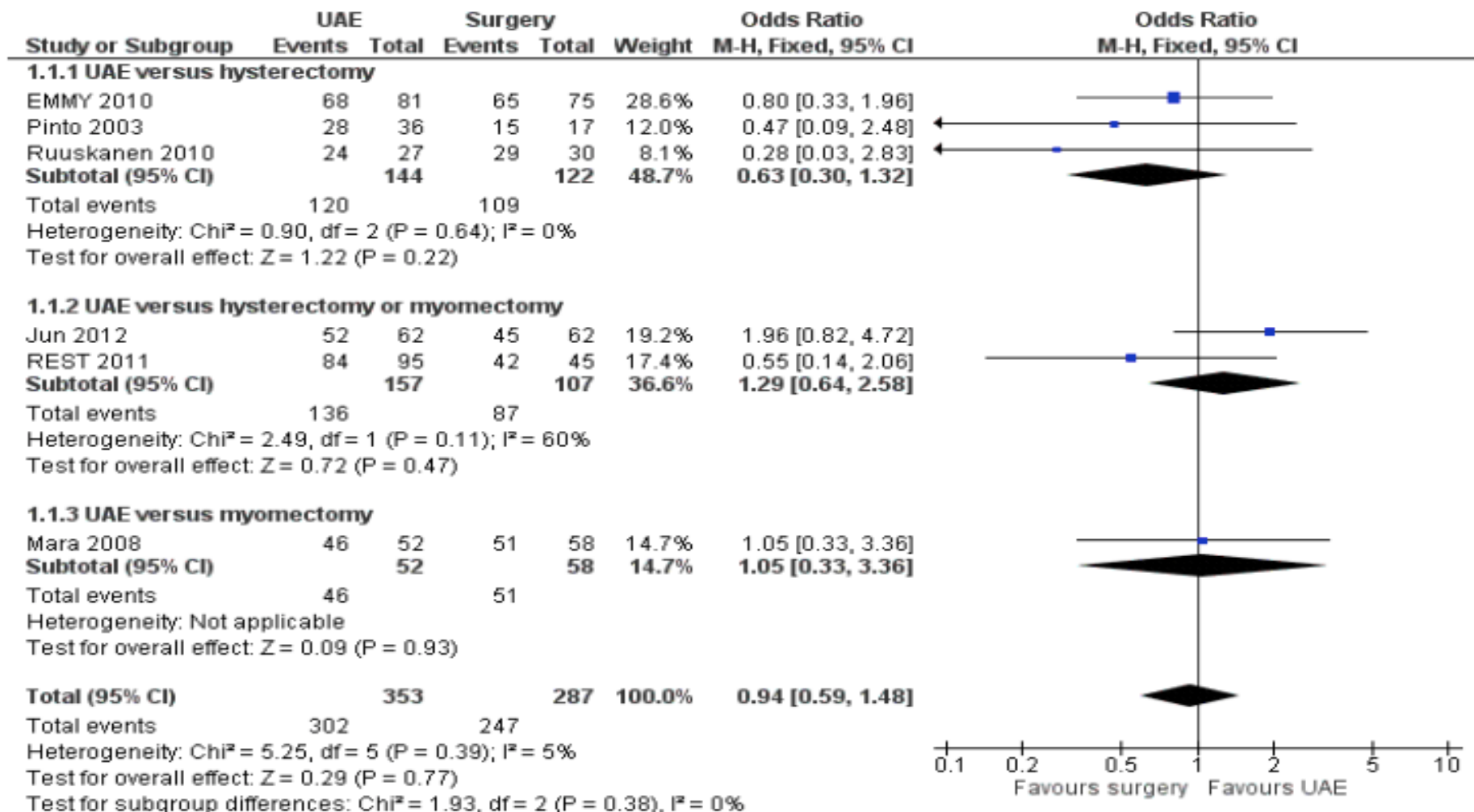
Patient satisfaction with the procedure

Toor, Sundeep; Jaber, Arash; Macdonald, D. Blair; McInnes, Mathew D.; Schweitzer, Mark E.; Rasuli, Pasteur. Complication Rates and Effectiveness of Uterine Artery Embolization in the Treatment of Symptomatic Leiomyomas: A Systematic Review and Meta-Analysis. *American Journal of Roentgenology* (AJR): 199, November 2012.

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**Figure 3. Forest plot of comparison: 1 UAE versus surgery, outcome: 1.1 Satisfaction with treatment up to 24 months.**

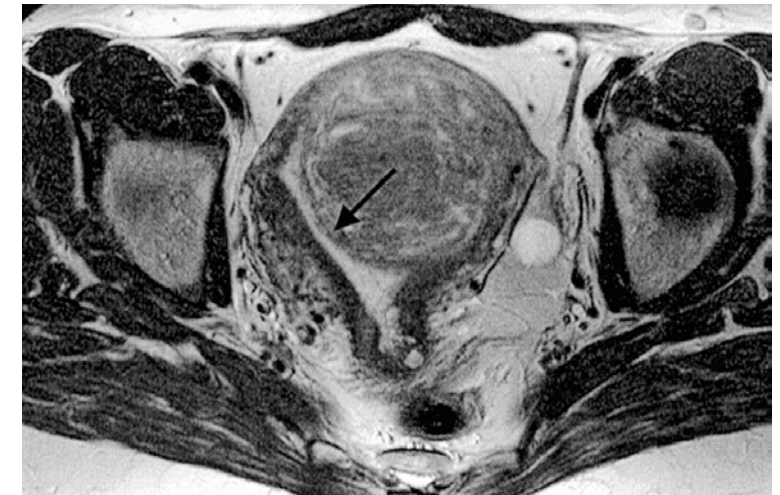


Gupta JK, Sinha A, Lumsden MA, Hickey M. Uterine Artery Embolization for Symptomatic Uterine Fibroids. Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD005073. DOI: 10.1002/14651858. CD005073.pub4.

# Clinical Outcomes – Complications

## Fibroid expulsion:

- Can occur weeks to months post-procedure
- Approximately 2.5% of patients
- Can range from mild discharge to expulsion of tissue, bleeding
- Often managed with supportive care
  - Antibiotics if infection suspected
- Hysteroscopic management may be necessary (0.8-1.7%)
- In worst case can result in hysterectomy (0.7%)



# Clinical Outcomes – Complication Rates

Low rate of overall complications and major complications

Overall complication rate 10.5% (79% within 30 days)

1.25% Serious complication rate (SIR class D or above)

PE, endometritis, bleeding due to fibroid passage

There were no class E or F complications in the study

Grade	Outcome
A	No therapy, no consequence
B	Nominal therapy, no consequence; includes overnight admission for observation only
C	Requires therapy, minor hospitalization (<48 hours)
D	Requires major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
E	Permanent adverse sequelae
F	Death

Raikhlin A, Baerlocher MO, Asch MR. Uterine Fibroid Embolization. *Canadian Family Physician* 2007 Feb; 53(2): 250-256.

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# Clinical Outcomes – Complication Rates

Complication	No. of Patients Available <sup>a</sup>	Pooled Rate (%) (95% CI)
Major	8159 (54)	2.9 (2.2–3.8)
Angiography related	6953 (44)	2.9 (2.1–3.9)
Infectious	7149 (49)	2.5 (1.8–3.2)
Fibroid passage		
Overall	6858 (41)	4.7 (3.9–5.7)
Assisted	6858 (41)	1.2 (0.8–1.7)
Unassisted	6832 (40)	3.4 (2.6–4.3)
DVT or PE	7632 (54)	0.2 (0.2–0.4)
Permanent amenorrhea	5173 (40)	3.9 (2.7–5.3)
Other events		
Hysterectomy for complication	4903 (53)	0.7 (0.5–0.9)
Readmission	6223 (37)	2.7 (1.9–3.7)
Technical success rate	7545 (48)	97.3 (96.7–97.9)

- 2-5%** Passage of fibroid (esp. submucosal, intracavitary)
- 2.7%** Readmission
- 2.5%** Allergic Reaction (can usually treat in office)
- 3-5%** Permanent amenorrhea (>90% of these over 45 y.o.)
- 0.7%** Complication resulting in hysterectomy
- <1%** Hemorrhage

Toor, Sundeep; Jaber, Arash; Macdonald, D. Blair; McInnes, Mathew D.; Schweitzer, Mark E.; Rasuli, Pasteur. Complication Rates and Effectiveness of Uterine Artery Embolization in the Treatment of Symptomatic Leiomyomas: A Systematic Review and Meta-Analysis. *American Journal of Roentgenology* (AJR): 199, November 2012

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# Clinical Outcomes – Research From Our Centers

**Safety of Uterine Artery Embolization Performed as an Outpatient Procedure:**  
**Retrospective analysis of 876 patients across a network of 26 outpatient interventional radiology practices.**

Guyer, Adam G; Raggio, Thomas C; Sor, Murat; Usvyat, Len; Latif, Walead; Gregg, Miller; Koh, Elsie; Rosenblatt, Mel; and Suchin, Craig

**CONCLUSION:** Our analysis demonstrates no significant difference with regards to fluoroscopy time, exposure dose, and contrast volume associated with UAE for leiomyomas as compared to the largest studies performed in the inpatient setting. This analysis suggests that UAE can be safely performed and managed as outpatient procedures with 0.57% of treatments requiring escalation of care.



# Conclusion

# Conclusion

UFE is performed safely and effectively in an outpatient setting.

UFE has similar long term outcomes to surgery but with faster recovery, no hospital stay (if done in our clinic), lower overall major complication rates, and low cost.

Our patients are extremely satisfied with the experience they have at our center

Fibroid embolization should be considered an important part of the treatment algorithm for symptomatic fibroids.

Information for patients can be found on our microsite and blog [www.infoufe.com](http://www.infoufe.com)

Thank you for attending

# Understanding the UFE Experience in an Outpatient Setting

For more information, contact:  
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7. Toor, Sundeep; Jaber, Arash; Macdonald, D. Blair; McInnes, Mathew D.; Schweitzer, Mark E.; Rasuli, Pasteur. Complication Rates and Effectiveness of Uterine Artery Embolization in the Treatment of Symptomatic Leiomyomas: A Systematic Review and Meta-Analysis. *American Journal of Roentgenology* (AJR): 199, November 2012.
8. Gupta JK, Sinha A, Lumsden MA, Hickey M. Uterine Artery Embolization for Symptomatic Uterine Fibroids. *Cochrane Database of Systematic Reviews* 2014, Issue 12. Art. No.: CD005073. DOI: 10.1002/14651858. CD005073.pub4.
9. Raikhlin A, Baerlocher MO, Asch MR. Uterine Fibroid Embolization. *Canadian Family Physician*, 2007 Feb; 53(2): 250-256.