Uterine fibroid embolization
Grand Rounds – May 2, 2018

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University of Kansas SOM-Wichita
Disclosures

• No financial disclosures relevant to this topic
Objectives

• Review the background and treatment options for patients with uterine fibroids
• Understand how fibroid patients are evaluated by IR
• Discuss the technical aspects of uterine fibroid embolization
• Describe clinical outcomes after uterine fibroid embolization
• Address challenges in uterine fibroid embolization
• Hear the story of a patient treated with UFE
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Uterine fibroids - background

• Benign fibromuscular tumor of the uterus

• Common problem

• Age, family history, race, and obesity are risk factors
Uterine fibroids - symptoms

• **Bleeding symptoms:**
  – Prolonged cycles
  – Bleeding in between cycles

• **Bleeding symptoms is probably where we do best**
Uterine fibroids - symptoms

• **Bulk symptoms:**
  – Fullness
  – Urinary frequency
  – Constipation
  – Back pain
  – Pain during sex
  – Infertility

• Take longer to resolve but still should see reduction
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Description</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormonal agents</td>
<td>Symptomatic relief; reduces bleeding; decreases tumor size</td>
<td>No procedure necessary; may be used as temporizing measure or adjunctive therapy to other treatments</td>
<td>Long-term treatment; consequences of menopausal-like symptoms and bone loss; high recurrence rate; fertility preservation may be dependent on subsequent procedures; temporary therapy, as symptoms recur when treatment ends</td>
</tr>
<tr>
<td>MRgFUS</td>
<td>Ultrasound waves penetrate anterior abdominal wall and heat fibroid tissue, causing cell death at focal points identified by MRI</td>
<td>Outpatient procedure; no surgical incision; no anesthesia necessary; short recovery time with minimal discomfort</td>
<td>Procedure requires 4 hours on average; not intended for large or numerous fibroids; currently limited data and limited third-party reimbursement</td>
</tr>
<tr>
<td>UFE</td>
<td>Nonsurgical, interventional radiologic procedure to nearly occlude uterine arteries (blood supply to fibroids)</td>
<td>No surgical incision; no anesthesia necessary; favorable recovery time; few major complications</td>
<td>Postembolization syndrome (pain, fever, leukocytosis) is common; fibroids/symptoms may recur, necessitating additional procedures</td>
</tr>
<tr>
<td>Endometrial ablation</td>
<td>Hysteroscopic destruction of the endometrium to reduce menorrhagia</td>
<td>Can effectively control menorrhagia despite presence of fibroids</td>
<td>May not be technically feasible in some patients with myomas in uterine cavity; will not reduce bulk symptoms</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>Open surgical or endoscopic excision of tumors</td>
<td>Symptom resolution with fertility preserved; minimal procedural blood loss (if done via laparoscopy)</td>
<td>Perioperative morbidity similar to hysterectomy; prolonged recovery (after open surgery); recurrence of tumors, persistent vaginal bleeding; success can be limited by number and extent of tumors</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>Surgical removal of uterus (may be transabdominal, transvaginal, or laparoscopic)</td>
<td>Definitive treatment</td>
<td>Loss of fertility; prolonged recovery (after open surgery); surgical risks dependent on type of procedure</td>
</tr>
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</table>
Uterine fibroids – US healthcare system

5 million women in the US at a cost of ~9 billion/year

"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.
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What is IR?

- Relatively new specialty
- Training pathways changing
What is IR?

- Treat people using imaging as guidance
- We do big things through small holes!
- UFE described dating back to 1995 with the first performed in USA in 1997 – now well over 100K done.
What is IR?
Patient evaluation for UFE

- Most of our patients (~80%) self-refer
- Allows us to do longitudinal care, admitting to our own service on these patients.
Patient evaluation for UFE

• **History and physical – key points:**
  – Menstrual history
  – Patient symptoms & prior therapies
  – Pregnancy history
  – Family history of fibroids or cancer
  – Blood thinning medicines
  – Allergies, especially to IV contrast
  – Uterine size measurements

• Need to know what you are treating in order to help the patient best.
  – What are their problems?
  – What are their expectations?
Patient evaluation for UFE

- **Laboratory values:**
  - Creatinine, platelets, INR
  - FSH, LH

- **Pathology results:**
  - Make sure that pap smear is up to date
  - Endometrial biopsy
MR has better spatial resolution than US and better assesses size and location of the fibroid. Additionally, can give us information on the enhancement of the fibroid, presence of gonadal arteries, and also looks for adenomyosis.
Patient evaluation for UFE
Figure 2. Pedunculated subserosal fibroid. Sagittal T2-weighted fast spin-echo (a) and contrast-enhanced three-dimensional (3D) T1-weighted fat-suppressed spoiled gradient-echo (b) images show an enlarged uterus with multiple fibroids. A subserosal fibroid (*) with a narrow pedicle (arrows) is noted. The diameter of the pedicle is greater than 2 cm. Both the pedicle and the fibroids enhance after contrast material administration.
Two studies (above) have looked at complications with pedunculated subserosal fibroids and found no detachment or increased complications.
Patient evaluation for UFE

1) Good procedure for *most* patients with symptomatic fibroids (*even if multiple*)
2) Not pregnant & do not wish future pregnancy
3) Avoid surgery or desire shorter recovery
4) Peri-menopausal (less chance for re-intervention)
5) Poor surgical candidates
Patient evaluation for UFE – predictors of good outcomes from FIBROID registry

1) Menorrhagia
2) Smaller uterine size
3) Dominant fibroid <12 cm in size
4) Multiple fibroids
5) Intra-mural and sub-mucosal fibroids
Patient evaluation for UFE – less than ideal

1) Large, submucosal fibroids
2) Large, pedunculated subserosal
3) Single large fibroid (> 12 cm)
4) Cervical fibroids
Patient evaluation for UFE – less than ideal

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Contraindications to UFE</th>
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<tbody>
<tr>
<td><strong>Absolute contraindications</strong></td>
<td></td>
</tr>
<tr>
<td>Current pregnancy</td>
<td></td>
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<tr>
<td>Known or suspected gynecologic malignancy</td>
<td></td>
</tr>
<tr>
<td>Current uterine or adnexal infection</td>
<td></td>
</tr>
<tr>
<td><strong>Relative contraindications</strong></td>
<td></td>
</tr>
<tr>
<td>Contrast material allergy</td>
<td></td>
</tr>
<tr>
<td>Coagulopathy</td>
<td></td>
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<tr>
<td>Renal failure</td>
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</tbody>
</table>

From Spies, J et al 2012
Fibroid patients to be considered primarily surgical:

- Pregnant or desires future pregnancy
- Uterus size of approximately 18 weeks gestation
- Main fibroid(s) or majority of fibroids are non-enhancing on MRI
- Primarily cervical fibroids
- Main fibroid(s) are pedunculated subserosal fibroids with a narrow stalk

Even with the above conditions, any woman who wants to avoid surgery should be referred to IR for discussion of uterine fibroid embolization
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Technical aspects of UFE

• NPO for procedure
• Moderate sedation
• Intra-procedural medications
  – ABX prophylaxis
  – Antiemetics
  – Pre-op, intra-procedure, post-procedure pain management
Arterial access – Trans-femoral
Arterial access – Trans-femoral

Positives – faster, more comfortable to operator, probably less radiation

Negatives – weird working angle, patient not able to ambulate
Trans-radial access

Positives – more comfortable to patient, better working angles, able to ambulate immediately

Negatives – learning curve
Uterine artery

- Branch off the anterior division of the internal iliac artery
- Contralateral oblique view is helpful
- Can access with either a 4F/5F diagnostic catheter or micro-catheter
Want to get out to “horizontal portion” of uterine so we missed cervico-vaginal branches that come off.

Also watch for ovarian supply – start with bigger beads.
Embolization

Goal of UFE is fibroid infarction

Embospheres from Merit Medical
Embolization technique
Embolization goals
Balancing act between post procedure pain and embolization end point.

Recurrent symptoms at 2.5 years post-embolization, new fibroids by 4 years
Pain management during UFE

JVIR 2001 – RCT (only 18 patients) but IA was delivered prior to embolization

IA lidocaine induces vasospasm

JVIR 2016 – RCT 60 patients – did well if delivered after embolization or during embolization.

IA lidocaine injected during or after embolization reduces analgesic requirements
Other techniques like intra-arterial Toradol and superior hypogastric nerve block are less well-studied.
Post-procedure and follow-up

• Most desire discharge same day

• Overnight observation on the IR service
  – Pain & nausea control
    • Mean pain score = 3 (1st 24 hours), avg peak score in 1st week = 4.8, less than 18% of women ever experience pain > 7 (Bruno J, et al 2004)

• Post-procedure follow-up in IR clinic at 3 weeks

• Follow-up in IR clinic in approximately 6 months after UFE
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Comparative effectiveness

Provides evidence on efficacy, benefits, risks, and costs of different treatment options

<table>
<thead>
<tr>
<th>Embolic Agent</th>
<th>Literature Support</th>
</tr>
</thead>
</table>

From Gary Siskin, 2017
Short term outcomes (12 months)

Selective uterine artery embolization as primary treatment for symptomatic leiomyomata uteri.
Hutchins FL Jr., Worthington-Kirsch R., Bergkowitz R.P.

305 patients; 3.6% re-intervention rate

Uterine artery embolization for leiomyomata.
Soles JB Jr., Ascher SA, Roth AR, Kim J, Levy EB, Gomez-Jorge J.

200 patients; 10.5% re-intervention rate


BULK  BLEEDING
92%  92%
90%  91%
88%  92%
# Long term outcomes

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

*From Spies, JB*
HOPEFUL study - Dutton S, et al BJOG 2007

• Retrospective multicenter trial comparing UFE (n=649) and hysterectomy (n=459)

• Mean follow-up: 8.6 years for hysterectomy, 4.6 years for UFE

• Endpoints:
  – Primary: Safety
  – Secondary: resolution of symptoms and patient satisfaction
HOPEFUL study - Dutton S, et al BJOG 2007

• Less complications with UFE (19% vs 26%; p=0.001)

• Hysterectomy patients had more symptom relief (95% vs. 85%; p<0.0001)

• UFE patients were more likely to recommend the procedure to a friend (91% vs 85%; p=0.007)
HOPEFUL study - cost analysis (Hirst A, et al 2008)

- Staged cost analysis (Hirst A, et al 2008)
  - I – Procedure costs, complications, loss of productivity
  - II – Costs associated with repeat procedures or recurrent symptoms

- Analysis at 44 years of age
  - Stage I - UFE with a lower mean cost (accentuated by loss of productivity)
  - Stage II – UFE had additional costs (but still not more), whereas hysterectomy did not

- Analysis at 35 years of age
  - Similar results as at 44 years but with more cost due to UFE
REST investigators – NEJM 2007

• Prospective, randomized trial comparing UFE (n=106) and hysterectomy (n=43)

• Endpoints:
  – Primary: quality of life at 1 year
  – Secondary: time to resume normal activities, satisfaction scores, pain scores at 24 hours, complications, treatment failure
REST investigators – NEJM 2007

• Hysterectomy associated with higher pain scores at 24 hours but better symptom control at 12 months

• UFE had shorter hospital stay & recovery

• High satisfaction scores for both procedures (87% vs. 90%) with no difference in QOL at 12 months
• Re-intervention rate for UFE was 13% at 12 months & 32% at 60 months

• Complications:
  – Minor: UFE = 34%; surgery = 20%
  – Major: UFE = 15%; surgery = 20%
EMMY trial
De Bruijn 2016

• Randomized, multi-center study including 177 patients with 1:1 randomization

• Endpoints:
  – Primary: Elimination of heavy/abnormal bleeding
  – Secondary: Re-interventions, quality of life, bladder and bowel function, menopausal symptoms, menstrual characteristics, patient satisfaction
  – Most secondary hysterectomies were due to persistent symptoms but a small number were due to complications during UFE
  – Way to look at this as glass half full/half empty
EMMY trial
De Bruijn 2016

• Improved QOL & patient high satisfaction in both groups

• Recovery and pain were better with UFE
EMMY trial – cost analysis

- Costs included health care costs in and out of the hospital as well as costs related to absence of work (societal perspective).
  - The mean total costs were lower for UFE ($11,626 vs. $18,563)
  - The direct medical in-hospital costs were lower for UFE ($6,688 vs. $8,313)
  - The costs related to absence from work were lower for UFE
- They concluded that the 24 month cumulative cost of UFE is lower than that of hysterectomy.

From Siskin, G 2017

But again as re-intervention rates start to climb at 2-5 and 5-10 years, maybe costs would increase as well.
UFE vs. myomectomy

- Prospective but non-randomized (patient choice) including 149 UFE patients & 60 myomectomy patients
UFE vs. myomectomy

- Both groups improved quality of life
- UFE had shorter hospital stay, quicker return to activity, & less complications
UFE vs. myomectomy

• Prospective study of 121 patients (UFE = 58, myomectomy = 63)

• Mean follow-up was 24.9 months

• Identified midterm clinical outcomes & reproductive results
UFE vs. myomectomy

- UFE was associated with quicker recovery & shorter hospital stays
- No significant differences between groups in technical success, effectiveness, re-interventions, or complications
## UFE vs. myomectomy

### Reproductive Outcomes

<table>
<thead>
<tr>
<th></th>
<th>UFE</th>
<th>Myomectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant/Tried to conceive (N)</td>
<td>13/26</td>
<td>31/40</td>
</tr>
<tr>
<td>Pregnancy Rate</td>
<td>50%</td>
<td>78%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>( P &lt; 0.05 )</td>
</tr>
<tr>
<td>Delivery Rate</td>
<td>19%</td>
<td>48%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>( P &lt; 0.05 )</td>
</tr>
<tr>
<td>Abortion Rate</td>
<td>64%</td>
<td>23%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>( P &lt; 0.05 )</td>
</tr>
<tr>
<td>Relative Risk to not get pregnant after UFE</td>
<td>2.22 (95% CI 1.11 &lt; RR &lt; 4.44)</td>
<td></td>
</tr>
<tr>
<td>Relative Risk not to deliver</td>
<td>1.54 (95% CI 1.08 &lt; RR &lt; 2.18)</td>
<td></td>
</tr>
<tr>
<td>Relative Risk to abort</td>
<td>2.79 (95% CI 1.25 &lt; RR &lt; 6.2)</td>
<td></td>
</tr>
</tbody>
</table>

From Spies, JB

• UFE with PVA particles vs. abdominal myomectomy

• End-points:
  – Primary – Quality of life
  – Secondary – LOS, complications, treatment failure, re-intervention

• Improvements in quality of life occurred in each group

• UFE had shorter hospitalization

• No difference in complication rates

• At 2 years, re-intervention rate was 14% of UFE and 3% for myomectomy
Systematic review from AHRQ – Dec 2017

Sufficient evidence. Uterine artery embolization (UAE) (high SOE) as well as high intensity focused ultrasound (low SOE) are effective for decreasing fibroid size/volume. Few other outcomes are well investigated for high intensity focused ultrasound. UAE studies reported improved outcomes for bleeding (high SOE), and quality of life (moderate SOE). Myomectomy and hysterectomy improved quality of life (both low SOE). Few well-conducted trials directly compared different treatment options. No studies were designed to evaluate expectant management, and evidence is insufficient to guide clinical care. Subsequent intervention ranged from 0 to 44 percent in studies that followed women after initial fibroid treatment. At 2-year followup, subsequent intervention rates were lowest for initial medical management and higher for UAE and myomectomy, especially among younger women. No individual characteristics of women or their fibroids were definitely associated with likelihood of intervention benefits or patient satisfaction. These findings were limited by the number and size of available studies. Using data from 160 studies, we estimated that among 10,000 women having surgery for presumed fibroids, between 0 and 13 will have a leiomyosarcoma detected. Of the surgical
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Survey of ~1,200 women in the United States (>18 yo)
Challenge 1 – patient education

• 62% of respondents overall (44% of those with fibroids) had never heard of UFE

• Only 54% of women with fibroids learned about UFE from their doctors (ie half of women heard about UFE from friends, online, etc).

• 20% of women think total hysterectomy is the only way to treat fibroids
Challenge 2 – physician education

5 million women in the US at a cost of ~9 billion/year

“Watchful Waiting” 3.4 Million
Uterine fibroid embolization 30,000
Surgery ~250,000
Drug Therapy 1.4 Million

Challenge 2 – physician education

Original Article

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

Robert K. Zurawin, MD*, John H. Fischer, II, MD, and Leah Amir, MS, MHA

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.
Challenge 2 – physician education

**Dr. Fischer:** I would suggest that both gynecologists and radiologists discuss all available treatment options with their patients who have uterine fibroids. From an interventional radiologist’s perspective, I can state that UFE, like all procedures, is not for everybody. In many patients, however, UFE and less invasive surgical options can be effective treatment alternatives to traditional surgery. As always, favorable outcomes are most dependent on patient selection. The collaborative efforts of gynecologists and radiologists in treating fibroids best serve the patients.

**Dr. Zurawin:** I recommend Dr. Fischer’s approach, which may be different from other radiologists who are offering UFE. His practice provides complete care for the patient. He will examine the patient, perform the procedure, and handle postoperative care, and he has a team of professionals who will support him. This is essential to making the process successful.

Patient selection is key – not for everybody but would suggest that a decent portion of women that are receiving hysterectomy would benefit from UFE (decreased LOS, quicker recovery, highly effective) and provide, at a minimum 70% of women wouldn’t need re-intervention.
Challenge 3 – pregnancy

Conclusion: Low-level evidence to suggest that pregnancy rates may not be lower than the age-adjusted population.
Spontaneous Pregnancy with a Live Birth after Conventional and Partial Uterine Fibroid Embolization.

Pisco JM¹, Duarte M¹, Bilhim T¹, Branco J¹, Cirurgião F¹, Forjaz M¹, Fernandes L¹, Pereira J¹, Costa N¹, Pisco JBM¹, Oliveira AG¹.

Abstract

Purpose To determine pregnancy rates after conventional and partial uterine fibroid embolization (UFE). Materials and Methods The study received institutional review board approval and all patients gave written informed consent. A retrospective analysis of data collected prospectively was performed between June 2004 and June 2014 in a cohort of 359 women (mean age, 35.9 years ± 4.8) with uterine fibroids and/or adenomyosis who were unable to conceive. The median follow-up period was 69 months (range, 6-126 months). Under local anesthesia, both uterine arteries were embolized. In 160 patients, partial embolization was intentionally performed to preserve fertility, which may be decreased after conventional UFE. In partial UFE, only the small arterial vessels to the fibroids were embolized, leaving the large vessels of the fibroids patent. The Kaplan-Meier method and Cox regression were used for the statistical analysis. Results During follow-up, 149 women became pregnant, 131 women had live births, and 16 women had several pregnancies, resulting in a total of 150 live newborns. It was the first pregnancy for 85.5% (112 of 131) of women. Spontaneous pregnancy rates at 1 year and 2 years after UFE were 29.5% and 40.1%, respectively. The probability of successful pregnancy with live birth at 1 year and 2 years was 24.4% and 36.7%, respectively. Clinical success for fibroid-related symptoms was 78.6% (282 of 359). A dominant submucosal fibroid and ischemia greater than or equal to 90% had greater likelihood of spontaneous pregnancy. Complication rates in patients treated with partial UFE (14.6%) were not greater than rates in patients treated with conventional UFE (23.1%, P = .04). Conclusion Conventional and partial UFE may be safe and effective outpatient procedures for women with uterine fibroids who want to conceive. © RSNA, 2017.
Challenge 3 – pregnancy

Although the evidence is still limited, in sum, UFE should not be first-line treatment for women with infertility due to fibroids or who have a strong desire to become pregnant. However, it is still an option for patients who are poor surgical risks due to comorbidities, prior surgery, or the extent of the fibroids. The evidence also suggests that successful pregnancy is possible after UFE;

From Spies, JB
Challenge 4 – adenomyosis

- Abnormal endometrial tissue within the myometrium
- Symptoms can mimic those of fibroids
- Initial thought that UFE was not good treatment

From Spies, JB
Uterine Artery Embolization for the Treatment of Adenomyosis: A Systematic Review and Meta-Analysis

Annefleur M. de Bruijn, MD, Marieke Smink, MD, Paul N.M. Lohle, MD, PhD, Judith A.F. Huirne, MD, PhD, Jos W.R. Twisk, PhD, Caroline Wong, BSc, Linda Schoonmade, MA, Wouter J.K. Hehenkamp, MD, PhD

Abstract
The effect of uterine artery embolization (UAE) on symptomatic adenomyosis was evaluated in a systematic review and meta-analysis. Four groups were evaluated: short-term (< 12 months) pure adenomyosis, short-term adenomyosis with fibroids (combined adenomyosis), long-term (> 12 months) pure adenomyosis, and long-term combined adenomyosis. Improvement of symptoms occurred in 83.1% (872/1,049) of patients. Reported symptom reduction was 4.8% greater in the short-term combined group ($P = .169$) and 11.4% greater in the long-term combined group ($P = .003$). Uterine volume was reduced in all patients at 3 months. The effects of UAE on symptom improvement and uterine volume reduction in patients with adenomyosis are encouraging.
Conclusions

• Fibroids are a common problem

• UFE is a safe, minimally-invasive alternative to surgery that is appropriate for most women

• Collaboration between IR and OB/GYN is essential for patient care
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Big thank you to…

• Andrew Gunn – University of Alabama – Birmingham (UAB)
• James Spies, MD – Georgetown University
• Kelvin Hong, MBBS – Johns Hopkins Hospital
• Gary Siskin, MD – Albany Medical Center (NY)
• WRG Board of Directors and Partnership
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