



# Uterine Fibroid Embolization

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## Evidence-based Review

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# Faculty Disclosure

James B. Spies, MD

I have no financial relationships to disclose.



# Evidence-based Medicine

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- Review of properly designed comparative trials to draw conclusions on therapies
- Study design characteristics
  - Population defined, incl. and excl. criteria
  - Power analysis included
  - Properly randomized
  - Blinded where possible
  - Equal care and follow-up of participants
  - Proper endpoints chosen
  - Intent to treat analysis



# Literature Search

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- Uterine leiomyoma AND embolization
  - Limits: Randomized clinical trials
- 17 articles from randomized studies
- 10 articles results of comparison to other therapies
  - REST Trial (UFE vs Surgery, primarily hysterectomy)
  - Emmy Trial (UFE vs Hysterectomy) (5 articles)
  - Pinto Trial (UFE vs Hysterectomy)
  - Mara Trial (UFE vs Myomectomy)(2 articles)
  - Hald Trial (Lap. UA occlusion vs UFE)



# Literature Search

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- 7 articles comparing technical aspects of UFE
  - PVA vs Embospheres
  - sPVA vs Embospheres
  - Goserlin + UFE vs UFE alone
  - Intra-arterial lidocaine vs none for pain management (2 articles)
  - Serum markers after UFE vs myomectomy



# Randomized Trials

## REST Trial\*

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- Randomized multi-center study in the UK
- 2:1 ratio of UFE to surgery patients
  - UFE 106 patients
  - Surgery 51
    - Hysterectomy 43
    - Myomectomy 8
- Primary outcome measure scores on SF-36 at 1 year.

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



# Randomized Trials

## REST Trial\*

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- Short-term Results
  - UFE less painful at 24 hours (VAS of 3.0 vs 4.6,  $P < .001$ ).
  - UFE shorter stay (1 vs. 5 days,  $P < .001$ ).
  - Return to work (20 vs 62 days,  $P < .001$ ).
  - No difference in adverse events:
    - Major events (15% UFE vs 20% surgery,  $P = .22$ ).
    - Minor events (34 UFE vs 20% surgery,  $P = 0.47$ ).

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



# Randomized Trials

## REST Trial\*

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- Mid-term Results (median follow-up 32 months)
  - No difference in SF-36 QOL domain scores at 12 months.
  - No difference in EuroQol scores at 12 months.
  - Better improvement scores for surgery at 12 months
    - Range: -5 markedly worse to +5 markedly improved
    - 4.3 for surgery vs 3.6 for UFE, P=.03
  - Both groups equally satisfied
    - Would recommend to friend: 88% for UFE vs 93% surgery, P=.32
  - UFE more likely to need re-intervention (21 for UFE vs 1 for surgery, P<.001)
    - 10 in first year, 11 in subsequent follow-up

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



# Randomized Studies

## Emmy Trial\*

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- Randomized trial of hysterectomy vs UAE completed in Netherlands.
  - 5 published papers since November 2005 on short-term, mid and long-term outcomes.
  - 177 patients (88 UAE, 89 hysterectomy) recruited in 34 centers.
  - Participant recruited from among patients who had agreed to hysterectomy.

\*Hehenkamp WJK, et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and post-procedural results from a randomized controlled trial. AJOG 2005; 193: 1818-29.



# Randomized Studies

## Emmy Trial\*

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- Key findings: Short-term
  - No difference in SIR major complications (4.9 vs 2.7%,  $p=0.68$ )
  - More frequent minor complications with UAE (58 vs 40%,  $p=.024$ )
- Higher re-admission for UAE (11.1% vs 0%,  $p=.003$ )

\*Hehenkamp WJK, et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and post-procedural results from a randomized controlled trial. *AJOG* 2005; 193: 1818-29.



# Randomized Studies

## Emmy Trial\*

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- Higher than previously reported failure rate for UAE.
  - Technical failure rate 5.3%
  - Procedural failure 17.3%
- Primary outcome is non-inferiority of UFE at 2 years.
  - UFE success in at least 75% of patients
- Additional mid-term results in press

\*Hehenkamp WJK, et al. Uterine artery embolization versus hysterectomy in the treatment of symptomatic uterine fibroids (EMMY trial): peri- and post-procedural results from a randomized controlled trial. *AJOG* 2005; 193: 1818-29.



# Randomized Studies

## Hysterectomy vs UFE: Pinto Trial\*

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- Two to one randomized comparison of UFE vs hysterectomy (Zelen method).
  - 38 randomized to UFE, 19 to hysterectomy
  - Shorter stay for UFE
    - UFE 1.71 days vs Hyst. 5.85 days,  $p < 0.001$
  - Shorter return to routine activities for UFE
    - UFE 9.5 days vs 36.2,  $p < 0.001$
  - No difference in complications
    - UFE 25% vs Hyst 20%,  $p = 0.8$
  - Menorrhagia improved in 86% of UFE patients.

\*Pinto I et al. Uterine fibroids: uterine artery embolization versus Abdominal Hysterectomy treatment- a prospective, randomized and controlled clinical trial. Radiology 2003;226:425-431.



# Randomized Studies

## Myomectomy vs UFE: Mara Trial: Initial Results\*

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- Sixty-three patients randomized
  - (30 UFE, 33 myomectomy (15 lap, 18 open), mean age 32 both groups.
  
- Short term:
  - UFE shorter stay (3.7 days vs 5.3,  $p < 0.001$ )
  
  - UFE shorter recovery ((13.6 days vs 30,  $p < 0.0001$ )
  
  - No difference
    - Major complications (UFE 10% vs myo 3%)
    - Basal FSH after treatment (UFE 7.9 IU vs myo 6.5 IU, NS)
    - Proportion with symptomatic relief (UFE 87.5 vs myo 93.3%)

\*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.



# Randomized Studies

## Myomectomy vs UFE: Prague Trial\*

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- Mid-term results
  - 121 patients randomized UFE vs Myomectomy
    - Myomectomies: 63
    - UFE: 58
  - Follow-up: 118 pts- Minimum 12 months, mean 24.9 months
- Most clinical outcomes no difference
- UFE higher re-intervention, (36% vs 6.1%,  $p=0.01$ )
  - Re-intervention routine on UAE if persisting fibroid > 5cm, or recurrent fibroid in UFE or myomectomy > 5 cm.

\*Mara M et al, Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. Cardiovasc Intervent Radiol 2007(Epub ahead of print).

# Randomized Studies

## Myomectomy vs UFE: Prague Trial\*

Reproductive Outcomes			
	UFE	Myomectomy	
Pregnant/Tried to conceive (N)	13 / 26	31 / 40	
Pregnancy Rate	50%	78%	P < 0.05
Delivery Rate	19%	48%	P < 0.05
Abortion Rate	64%	78%	P < 0.05
RR not to get pregnant after UFE	2.22 (95% C.I. 1.11 < RR < 4.44)		
RR not to deliver	1.54 (95% C.I. 1.08 < RR < 2.18)		
RR to abort	2.79 (95% C.I. 1.25 < RR < 6.22)		

\*Mara M et al, Midterm clinical and first reproductive results of a randomized controlled trial comparing uterine fibroid embolization and myomectomy. Cardiovasc Intervent Radiol 2007(Epub ahead of print).



# Laparoscopic occlusion vs UFE

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- Randomized study of 58 patients from Ulleval University, Oslo Norway\*
- Primary outcome: change in blood loss by PBLAC at 6 months.
- Results:
  - Reduction on PBLAC similar , but UFE had fewer patients w/ continued heavy bleeding at 6 months (p= .044)
  - Greater post-op pain with UFE (VAS 5.5 vs 3.7, p-.026)
- Study weaknesses: No MRI with contrast follow-up. Key question is fibroid infarction rate, which was not investigated. Underpowered study (52% power to detect a 20% difference in bleeding change). Short-term follow-up only.

\*Hald K, Klow NE, Qvigstad E, Istre, O. Laparoscopic occlusion compared with embolization of uterine vessels: a randomized controlled trial. *Obstet Gynecol* 2007;109:20-7.



# Conclusions

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- Randomized comparative studies appearing that shed light on comparative outcomes.
- Uterine embolization has rapid recovery for most patients with few major complications when compared to surgery.
- It appears that for 80 to 90% of patients, UFE provides excellent symptom control for up to 3 years and beyond.
  - Symptom recurrence after UFE more likely than surgery in REST trial
- Reproductive outcomes after myomectomy may be better than after UFE.