

# Updates in fibroid management

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Wednesday, July, 24 , 2024



- I have no disclosures

# The Problem....

**Estimated \$34 billion in health care costs associated with fibroids in the United States.**

(Cardozo ER, Clark AD, Banks NK, Henne MB, Stegmann BJ, Segars JH. The estimated annual cost of uterine leiomyomata in the United States. *Am J Obstet Gynecol* 2012;206(3):211.e1-9.)

**Conversely, \$646M on urologic disorders.**

<https://report.nih.gov/funding/categorical-spending#>.

# Today's goals....

## Learn about

Participants will learn about risks, benefits, outcomes, and patient selection for medical and surgical options to treat leiomyoma.

## Be

Participants will be able to determine which patients are good candidates for which therapy.

## Be

Participants will be able to counsel patients on treatments for fibroids appropriate for them.

## Have

Patients will have appropriate counseling regarding all available treatment options for leiomyoma.

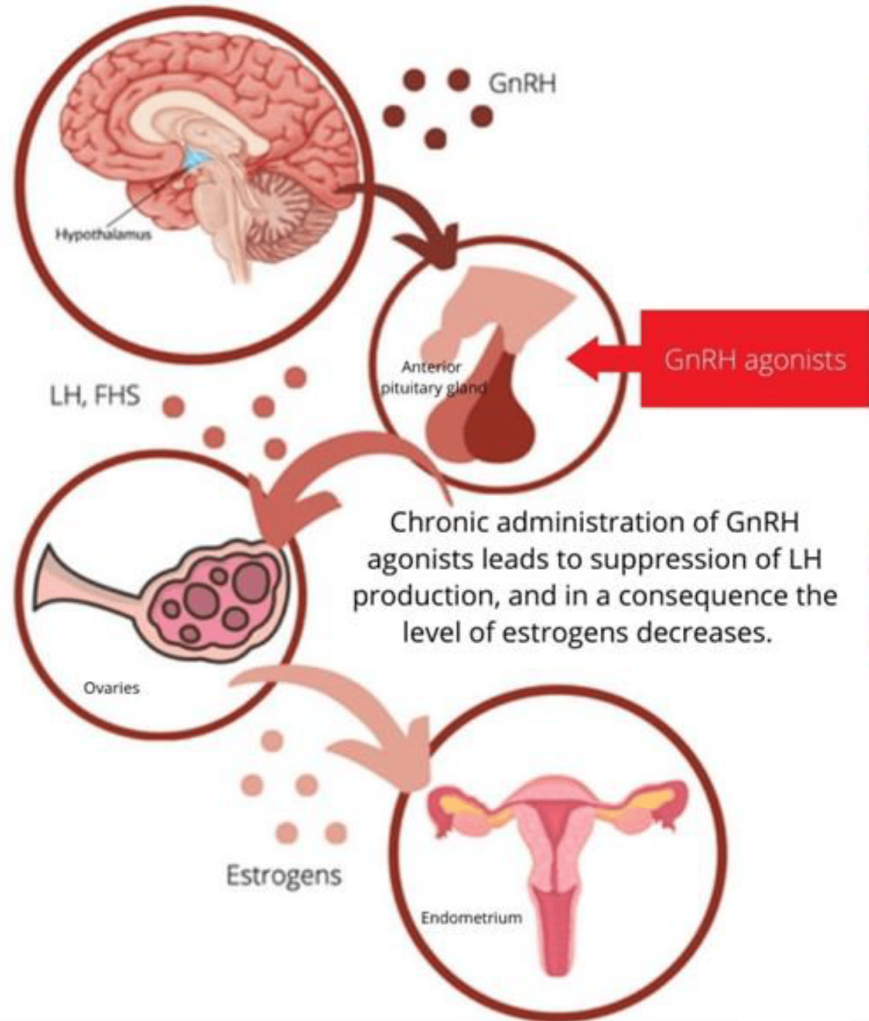


- Medical: GnRH antagonists, TXA
- Procedural: HIFU, UAE
- Surgical: Laparoscopic RFA, Transcervical RFA

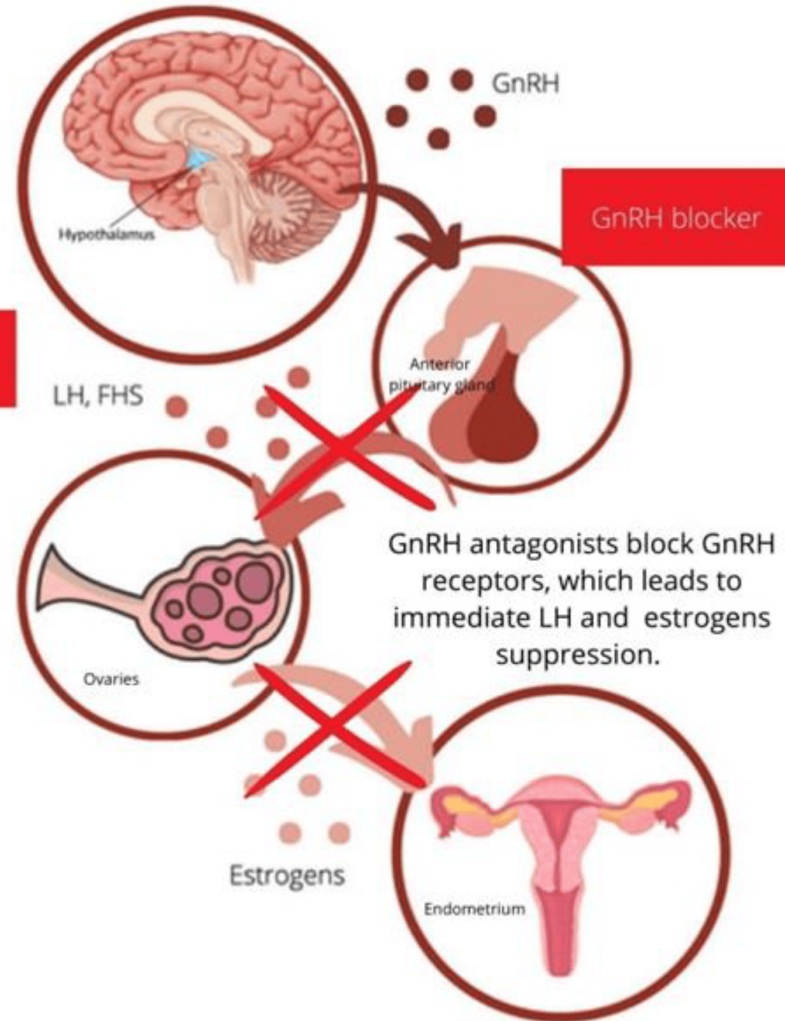
Medical



## GnRH agonists



## GnRH antagonists



# GnRH antagonists

- GnRH antagonist-> ↓ FSH, LH
- Back up non-hormonal contraception
- Limited to 24 months due to risk of bone loss which may be irreversible
- Baseline and periodic DEXA recommended
- Relugolix: Most common adverse reactions (>3%) vasomotor symptoms, AUB, alopecia, and decreased libido
- Elagolix: Most common adverse reaction (>5%) in clinical trials were hot flushes, headache, fatigue, metrorrhagia.



# Elagolix









- One capsule (elagolix 300 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) in the morning and one capsule (elagolix 300 mg) in the evening for up to 24 months.
- FDA approved for treatment of HMB associated with fibroids 5/2020



# Relugolix

- Relugolix 40mg, estradiol 1mg, and norethindrone 0.5mg once daily
- FDA approved for treatment of HMB associated with fibroids in 2021
- Warnings: hx of VTE or thromboembolic disorder, over 35+ smoking, uncontrolled HTN, pregnancy, osteoporosis, hormone sensitive malignancies, hepatic impairment, undiagnosed AUB, mood disorders



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# Liberty Trials



Advanced

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Clinical Trial > [Am J Obstet Gynecol.](#) 2023 Mar;228(3):320.e1-320.e11.

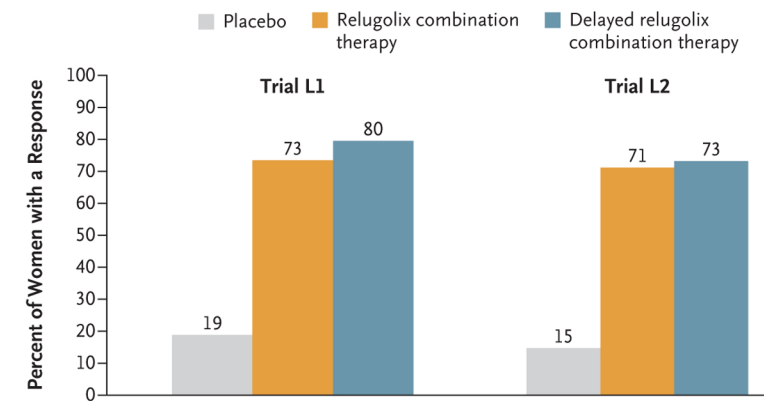
doi: 10.1016/j.ajog.2022.11.1278. Epub 2022 Nov 9.

## Quality of life with relugolix combination therapy for uterine fibroids: LIBERTY randomized trials

Elizabeth A Stewart<sup>1</sup>, Andrea S Lukes<sup>2</sup>, Roberta Venturella<sup>3</sup>, Yulan Li<sup>4</sup>, Elke Hunsche<sup>5</sup>, Rachel B Wagman<sup>4</sup>, Ayman Al-Hendy<sup>6</sup>

Affiliations + expand

PMID: 36370871 DOI: [10.1016/j.ajog.2022.11.1278](#)



	No. of Patients	127	128	132	129	125	127
Difference vs. Placebo — percentage points (95% CI)			55 (44–65)	61 (51–70)		56 (46–66)	58 (49–68)
P Value vs. Placebo			<0.001			<0.001	

# QOL



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Clinical Trial > [Am J Obstet Gynecol.](#) 2023 Mar;228(3):320.e1-320.e11.

doi: [10.1016/j.ajog.2022.11.1278](#). Epub 2022 Nov 9.

## Quality of life with relugolix combination therapy for uterine fibroids: LIBERTY randomized trials


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Affiliations + expand

PMID: 36370871 DOI: [10.1016/j.ajog.2022.11.1278](#)

**Conclusion:** "After 24 weeks of treatment with relugolix combination therapy, women with symptomatic uterine fibroids experienced substantial improvements in health-related quality of life with all subscales showing improvement, including emotional well-being, physical and social activities, and sexual function. In addition, women reported substantial reductions in the overall symptom burden and distress caused by key fibroid-associated symptoms."

# Modest Reduction in Fibroid size

 The NEW ENGLAND JOURNAL of MEDICINE

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ORIGINAL ARTICLE f X in ✉

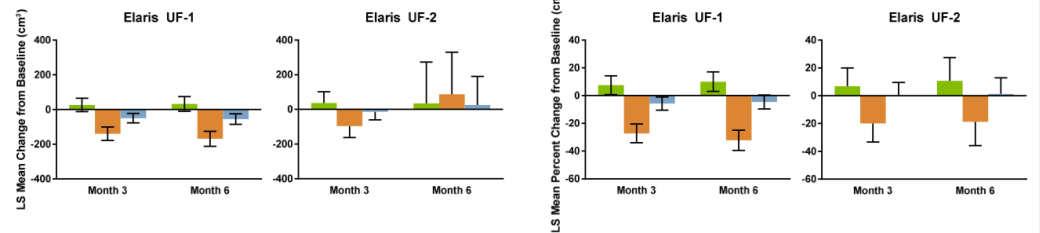
## Elagolix for Heavy Menstrual Bleeding in Women with Uterine Fibroids

**Authors:** William D. Schlaff, M.D., Ronald T. Ackerman, M.D., Ayman Al-Hendy, M.D., Ph.D., David F. Archer, M.D., Kurt T. Barnhart, M.D., Linda D. Bradley, M.D., Bruce R. Carr, M.D., [+13](#), and Ozgul Muneyirci-Delale, M.D. [Author Info & Affiliations](#)

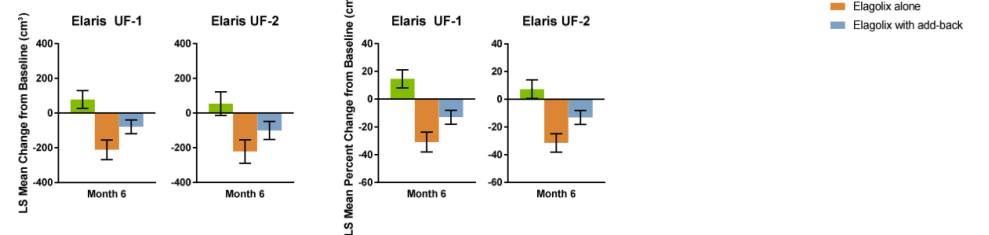
Published January 22, 2020 | N Engl J Med 2020;382:328-340 | DOI: 10.1056/NEJMoa1904351 | [VOL. 382 NO. 4](#)

**Figure S4.** Mean Change and Percent Change from Baseline in Uterine Volume During the Treatment Period by Pelvic Ultrasound and MRI

A. Pelvic ultrasound (TAU and/or TVU)



B. MRI



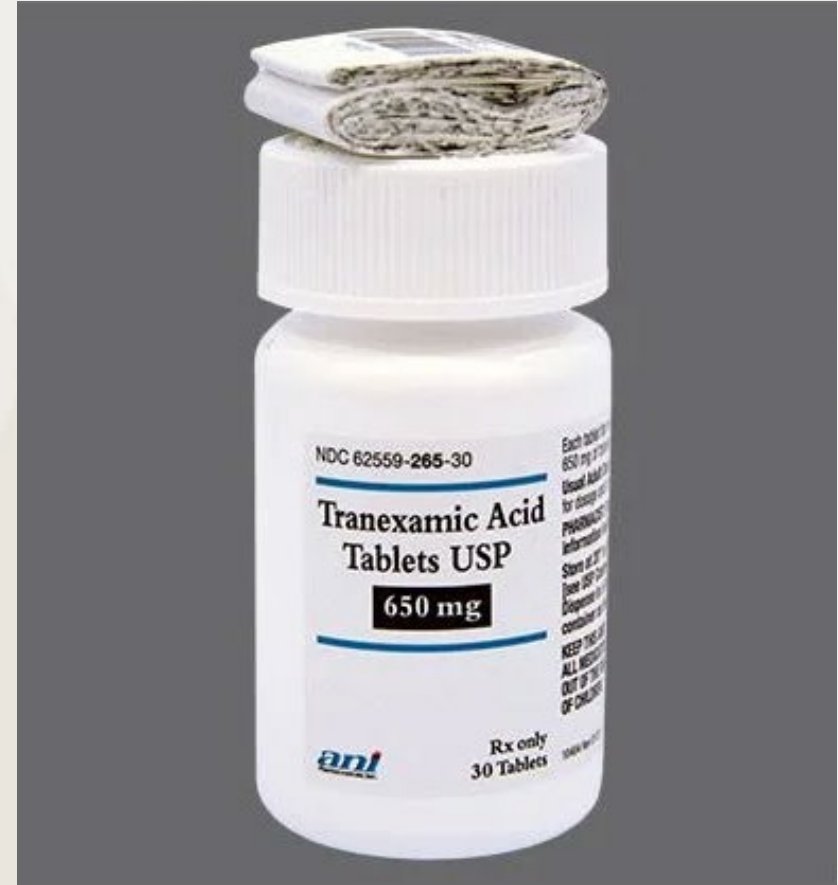
MRI = magnetic resonance imaging; TAU = transabdominal ultrasound; TVU = transvaginal ultrasound  
Data are least-squares means with error bars representing 95% confidence interval that were not adjusted for multiplicity. Change and percent change from baseline to each visit in uterine volume were analyzed using an ANCOVA model with treatment as the main effect and baseline uterine volume as a covariate.

# Medical options

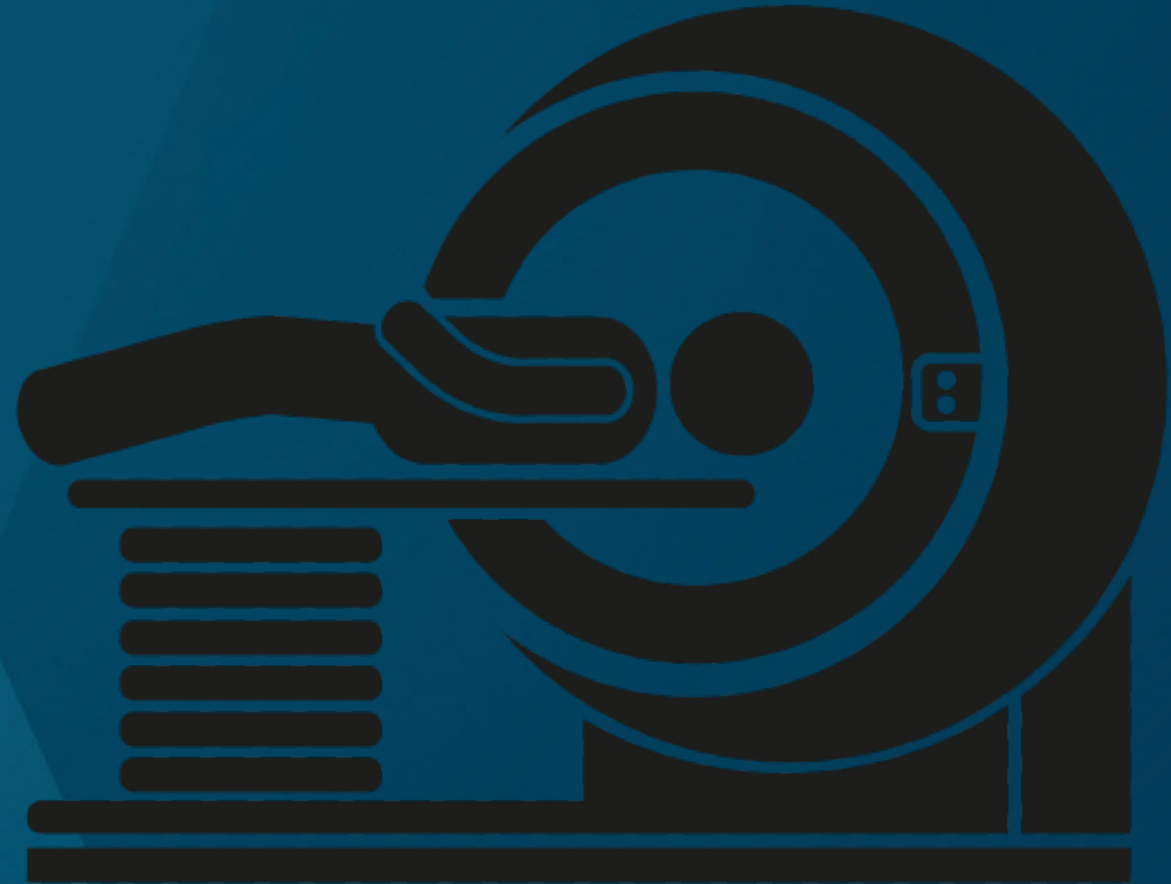
TXA (Lysteda)

Anti-fibrinolytic

FDA approved  
2009 for  
treatment of HMB.



Procedural

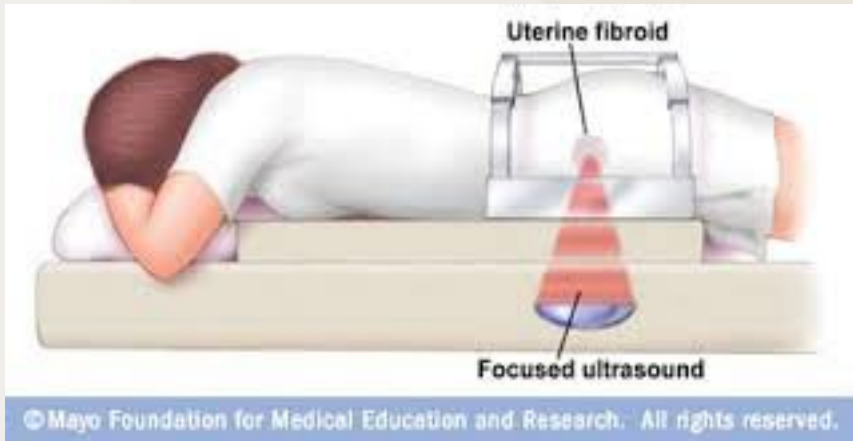




# HIFU or MRgFUS

Generally good outcomes, comparable or better than surgery. Reasonable post procedural fertility data.

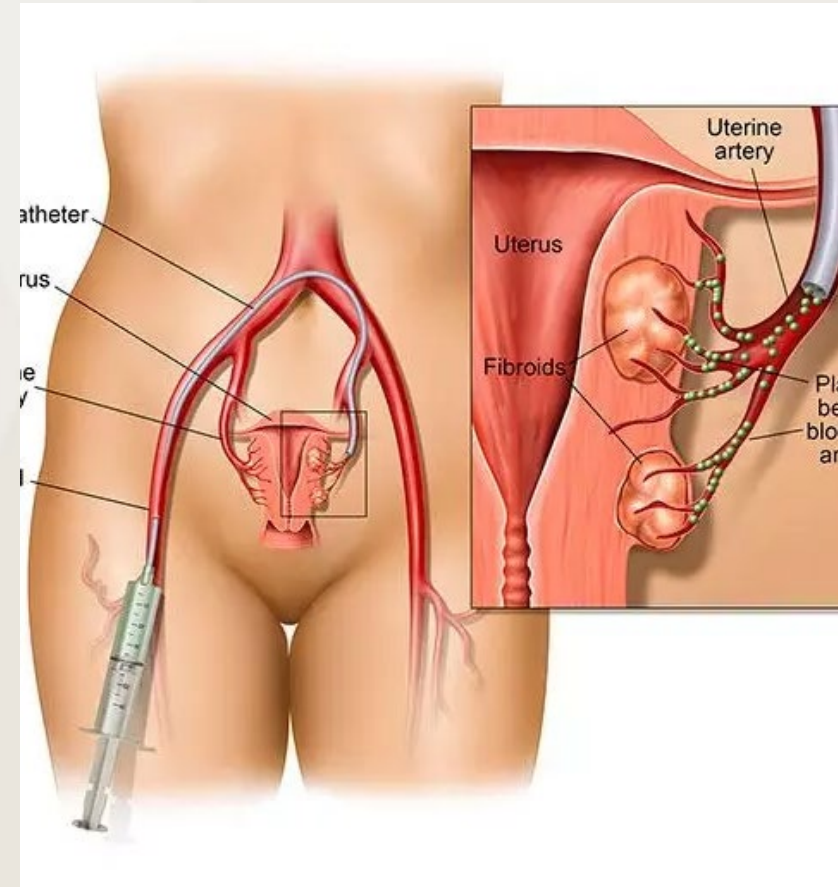
- Limitation is candidacy
- Fibroids less than 10cm
- Can't work for fibroids in posterior wall or near sacrum, acoustic window must be present
- Bowel between beam and target
- Subcutaneous tissue thickness
- About 3 hours



1. Patel N, Chaudhari K, Patel D, Joshi J. High-Intensity Focused Ultrasound Ablation of Uterine Fibroids: A Review. *Cureus*. 2023 Sep 4;15(9):e44680. doi: 10.7759/cureus.44680. PMID: 37809132; PMCID: PMC10550780.
2. Bryant K, LeBlang S. Patient selection guidelines for magnetic resonance focused ultrasound (MRgFUS) treatment: an updated view. *J Ther Ultrasound*. 2015 Jun 30;3(Suppl 1):P86. doi: 10.1186/2050-5736-3-S1-P86. PMCID: PMC4489172.

# Uterine artery embolization

- Performed since 1995
- Desire for fertility relative contraindication
- Average fibroid size decrease after technically successful procedure ~60%
- Contraindications: Large size (variable cut offs), Pedunculated fibroids, Undiagnosed bleeding
- Potential complications: post-embolization syndrome, PE

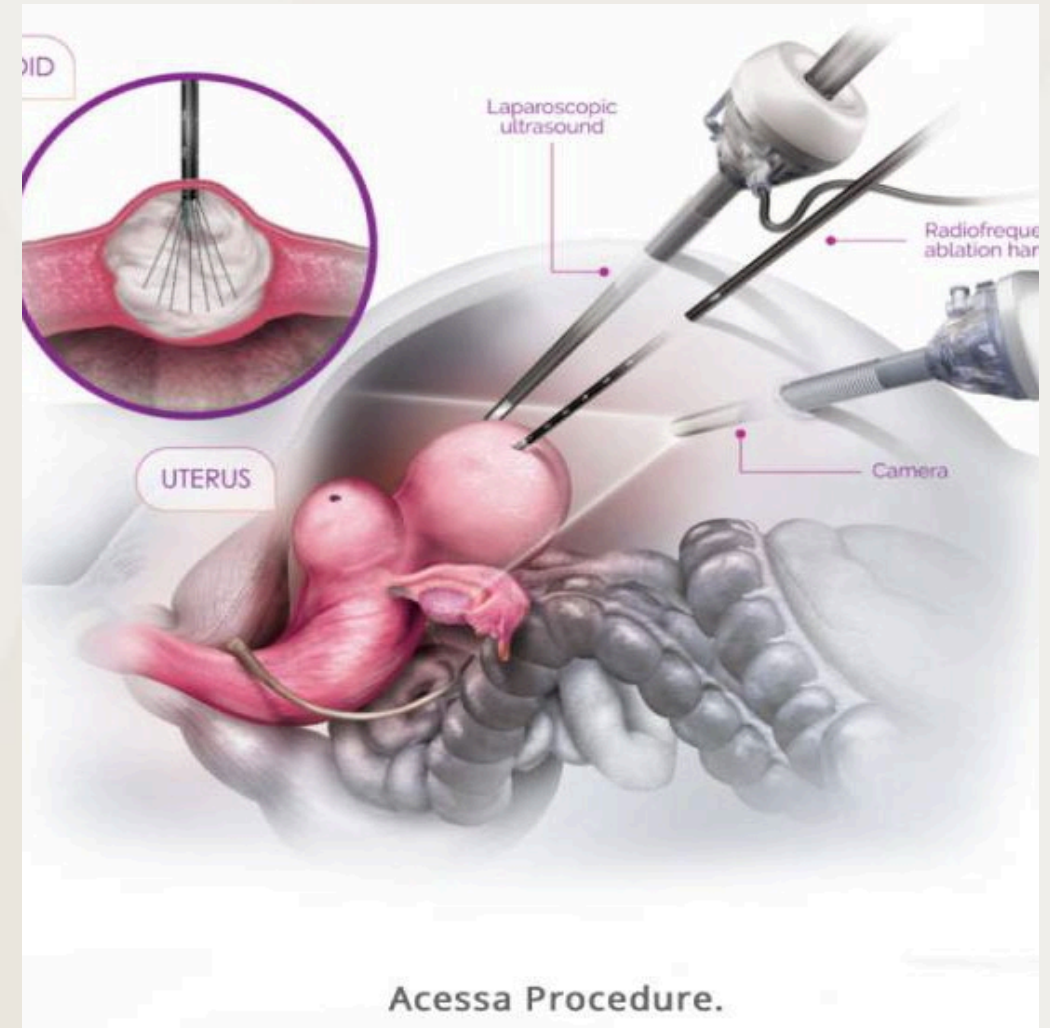


Surgical



# Laparoscopic radiofrequency ablation

- FDA approved Nov 2012
- “In a pivotal prospective, multicenter clinical trial (n = 137), Lap-RFA effectively decreased fibroid symptom severity, reduced menstrual blood loss, and enhanced health-related quality of life at 3 months post-treatment, with benefits sustained at 36 months.”
- Berman JM, et al. Three-year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *J Minim Invasive Gynecol.* 2014;21(5):767–774.



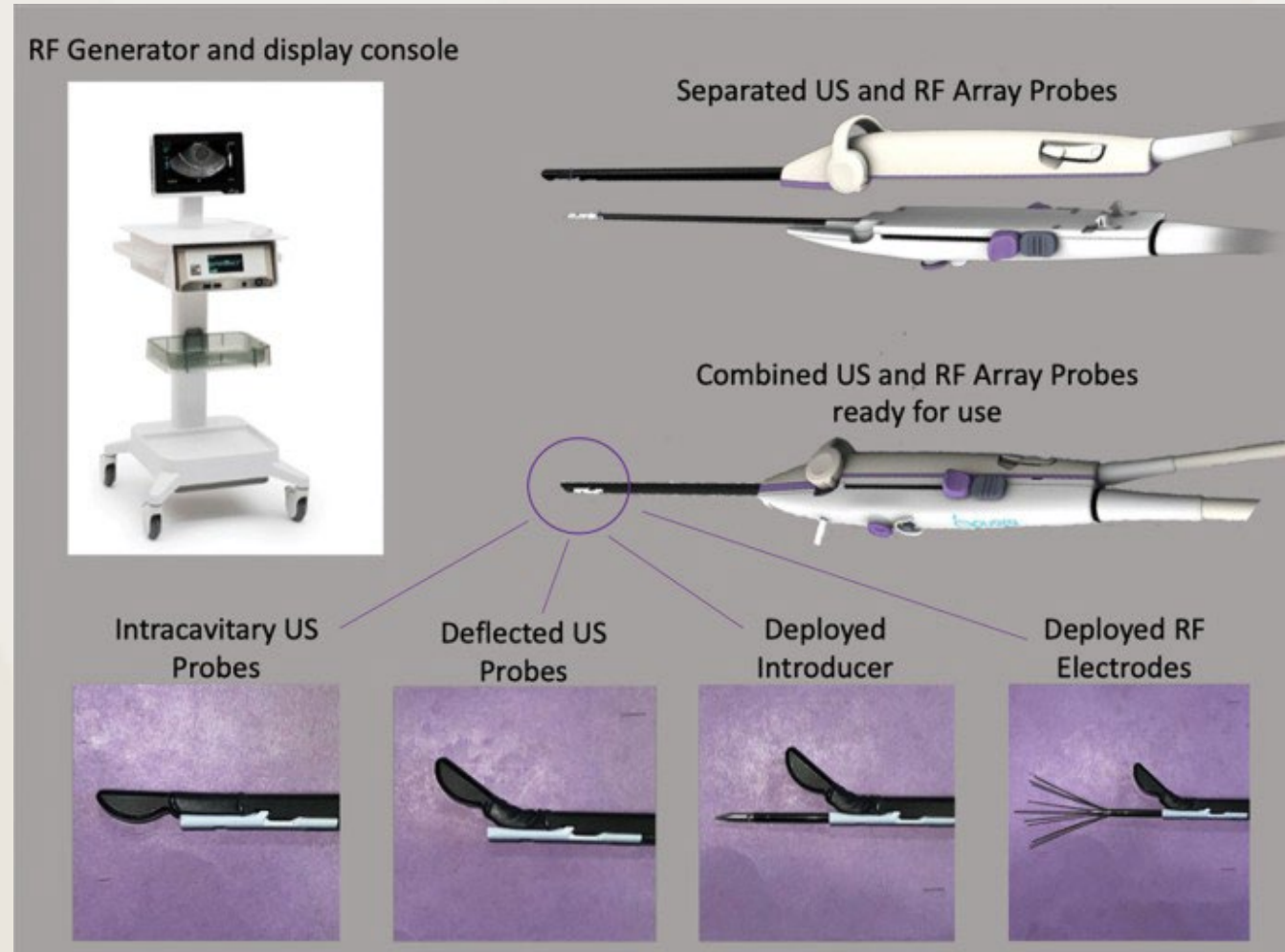
# Lap RFA: Procedural considerations

- Tissue reaches 95 degrees C
- FIGO 2-6
- Caution in type 7, (stalk less than 50% width)
- Treatment of 70-80% of volume of each fibroid rec
- “Heat sink” if near vessels
- Consider avoiding luteal phase
- Leiomyoma larger than 7cm or uteri larger than 14cm\*
- Metal in hips or unremovable metal jewelry of vulva or abdomen
- Antibiotics not specifically recommended, but given in trials



# Transcervical RFA

- Sonata system FDA approved 2018
- 125 patients over 12 months
- Mean maximal fibroid volume reduction per patient was 63.8%.
- Symptoms improved in 97% of patients.
- 1 patient moved to hyst



Hudgens J, Johns DA, Lukes AS, Forstein DA, Delvadia D. 12-month outcomes of the US patient cohort in the SONATA pivotal IDE trial of transcervical ablation of uterine fibroids. *Int J Womens Health*. 2019 Jul 5;11:387-394. doi: 10.2147/IJWH.S201912. PMID: 31308763; PMCID: PMC6616301.

# Transcervical RFA: Procedural considerations

- Dilate to 27F
- FIGO 1-6
- Avoid cervical, broad ligament, subserosal, or pedunculated submucosal
- Endometrial cavities <4.5cm avoid
- Metal in hips or unremovable metal jewelry of vulva or abdomen
- Leiomyoma larger than 7cm or uteri larger than 14cm



# Lap-RFA: Post-market



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## Postoperative Multibip

Raphael Niddar



Aubert Agostini,

Published: Mar

IMAGES IN GYNECOLOGICAL SURGERY | VOLUME 29, ISSUE 10, P1123-1124, OCTOBER 2022

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## Postoperative Uterine Necrosis Laparoscopic Radiofrequency

Emily Lin, MD   • Emily Sendukas, MD • Kimberly A. K

Published: June 09, 2022 • DOI: <https://doi.org/10.1016/j.jmig>



# RFA: Outcomes

Intervention	Ideal Leiomyoma Characteristics	Approach	Notable Side Effects or Risks	Leiomyoma Volume Reduction at 12 mo (%)	UFS-QoL HRQL Score Increase <sup>34</sup>	Reintervention Rate at 36 mo (%)
L-RFA	FIGO 2–6, less than 7–10 cm	Laparoscopic 10 mm+5-mm incisions, percutaneous puncture	Pelvic infection (rare)	45.1 <sup>14</sup>	38.6 (36 mo) <sup>23</sup>	11.0 <sup>23</sup>
TC-RFA	FIGO 1–6, less than 7–10 cm	Cervical dilation	Leiomyoma sloughing, leukorrhea	62.4 <sup>20</sup>	43.7 (36 mo) <sup>27</sup>	8.2 <sup>27</sup>
Myomectomy	FIGO 0–7, any size	Hysteroscopic, laparoscopic, minilaparotomy, or abdominal	Blood loss, greater LOS, surgical complications	100	47.6 (24 mo) <sup>35</sup>	11.0 <sup>36</sup>
UAE	FIGO 3–6, less than 10 cm	Endovascular incision	Pain, transient fevers	62.8 <sup>37</sup>	41.4 (24 mo) <sup>38</sup>	17.0 <sup>36</sup>
MRgFUS	FIGO 3–6, less than 7 cm	No incisions	Skin reaction	25.9 <sup>37</sup>	19.3 (24 mo) <sup>38</sup>	34.7 <sup>36</sup>

UFS-QoL HRQL, Uterine Fibroid Symptom and Quality of Life, Health Related Quality of Life; L-RFA, laparoscopic radiofrequency ablation; FIGO, International Federation of Gynecology and Obstetrics; TC-RFA, transcervical radiofrequency ablation; LOS, length of stay; UAE, uterine artery embolization; MRgFUS, magnetic resonance imaging-guided focused ultrasound surgery.

Radiofrequency Ablation of Leiomyomas. Stewart, Kelsey A. MD; Greenberg, James A. MD; Kho, Kimberly A. MD; Cohen Rassier, Sarah L. MD, MPH. *Obstetrics & Gynecology* 141(6):p 1063-1071, June 2023. | DOI: 10.1097/AOG.0000000000005196

# RFA: Pregnancy

**Conclusion:** "Almost all pregnancies after RFA of myomas were full-term deliveries with no maternal or neonatal complications. These findings add to the literature that radiofrequency myoma ablation may offer a safe and effective alternative to existing treatments for women who desire future fertility."

Polin M, Hur HC. Radiofrequency Ablation of Uterine Myomas and Pregnancy Outcomes: An Updated Review of the Literature. *J Minim Invasive Gynecol.* 2022 Jun;29(6):709-715. doi: 10.1016/j.jmig.2022.01.015. Epub 2022 Feb 2. PMID: 35123041.



# A Novel Endoscopic Robot Used for Operative Hysteroscopy

Authors: Lara Harvey MD, MPH, Richard Hendrick PhD, Neal Dillon PhD,  
Evan Blum BS, Lauren Branscombe MS, Scott Webster PhD, Robert J.  
Webster PhD, Ted Anderson MD, PhD

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