Panel 2 - RF Frequency Ablation of Uterine Fibroids - The New Frontier
Professional Education Information

Target Audience
This educational activity is developed to meet the needs of surgical gynecologists in practice and in training, as well as other healthcare professionals in the field of gynecology.

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Panel 2-RF Frequency Ablation of Uterine Fibroids - The New Frontier

Co-Chairs: Kimberly Kho

Faculty: Jessica Shepherd, Craig J. Sobolewski

To discuss the use of radiofrequency ablation technology for the treatment of uterine disorders. We will provide a review of the technology, its development for applications in gynecology, and provide an update of outcomes data. High volume surgeons will share their experiences with RF fibroid ablation and provide practical tips for implementation into our treatment armamentarium.

Learning Objectives: At the conclusion of this course, the participants will be able to: 1) Specify radiofrequency ablation technology and its applications in gynecologic surgery; 2) discuss the most recent clinical outcomes data for laparoscopic and transvaginal radiofrequency; and 3) review surgical tips and tricks and best practices for implementation into a comprehensive fibroid treatment program.

COURSE OUTLINE

3:15 pm  Welcome and Introduction  K.A. Kho
3:20 pm  The Need for Alternative/Non-extirpative Options for Fibroid Management  K.A. Kho
3:35 pm  Technology Review and Surgical Tips/Tricks/Insights  C.J. Sobolewski
3:50 pm  The Patient Experience and Integrating RF Ablation into Practice  J.A. Shepherd
4:05 pm  Questions & Answers
4:15 pm  Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop (listed in alphabetical order by last name).

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FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).

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Consultant: Myovant Sciences
Jessica Shepherd, MD, MBA
Consultant: Hologic, Myovant, Abbvie, Acessa Health, for; Abbvie, Acessa Health, and Cynosure
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Speakers Bureau: Medtronic, CooperSurgical
Paid Speaker: Hologic

Content Reviewers have nothing to disclose.
Asterisk (*) denotes no financial relationships to disclose.

All relevant financial relationships noted have been mitigated.

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Speakers Bureau: Covidien
The Need for Non-extirpative Options for Fibroid Management

Kimberly Kho, MD, MPH
Director, Fellowship in Minimally Invasive Gynecologic Surgery
Vice Chief of Staff & Associate Chief of Gynecology
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Learning Objectives

- To discuss the use of non-extirpative procedures for management of fibroids and fibroid-related symptoms
- To briefly review the comparative data of UFE
- To enhance understanding of pathophysiology
- To synthesize the current outcomes data on RF ablation of fibroids
- To discuss patient selection and procedural details

Why we need alternatives to hysterectomy...

• For women who want to manage symptoms but retain their uterus, myomectomy has been the gold standard
• Complication rates as high as 3-16% in surgeon-reported series
• 25% complication rate in analysis of insurance claims database
• 5% risk of hemorrhage or transfusion
• Often commit patients to subsequent cesarean section
• Recovery 15-30 days
• Re-intervention at 5 years
• 22% for additional uterine-sparing procedure
• 16% undergo subsequent hysterectomy

Understanding what patients want

- Survey of 500 women with self-reported symptomatic fibroids
- Women wait average 3.6 year before seeking care for fibroids
  - 32% wait more than 5 years
- 55% expressed fear of needing a hysterectomy
- 79% want to avoid invasive surgery or long recovery times
- Patients are requesting uterine-preserving options... regardless of desire for future fertility, childbearing
  - 51% wanted uterine-preserving options (65% in women <40 yrs)
  - 79% wanted treatment options that did not involve invasive surgery
FEMME Trial (2020)

- Introduced in 1995 for treatment of fibroids
- Prognostic factors
  - Menstrual bleeding scores were similar between groups
  - Ovarian failure: variable data

Reproductive outcomes

- Assessed fertility outcomes
- Racial diversity
- Strengths
  - Goal is for thermal energy @ 95-100'C and coagulative necrosis
  - Heat spreads by conduction through the fibroid
  - Heat falls off with distance from electrode (1/d^4)

Compared to UAE, rather than a global therapy, these are targeted treatments of fibroids

RCT comparing RFA to Laparoscopic Myomectomy: decreased hospital stay, lower EBL

Indicated for patients who are premenopausal w/ HMB, no desire for future pregnancy (?)

Initially conceived of us a preoperative adjunct to hysterectomy

HMB (vs bulk), smaller fibroids, SM location

Need for subsequent treatment:
- Bulk sx: 66 vs 69% improvement at 2 yrs (EMMY)
- Pelvic pain/dysmenorrhea: comparable to hysterectomy w/ @ 85% vs 78% at least moderately improved (EMMY)

Sonata, FDA approved in 2020

Acessa, FDA approved in 2012

Over 3-12 months, absorption of fibroid results in 47-66% fibroid volume reduction

Technology developed from solid liver and bone tumors

Does not incite infarction-related post-embolization syndrome

Additional procedures performed
- No difference in perioperative and postoperative complication rates between groups
- At 2 years, 84% (UAE) vs 56% (myomectomy) would recommend respective procedures to a friend
- Health-related QoL outcomes better for myomectomy - open (82%), laparoscopic (9%), hysteroscopic (3%) at 6 months, 1 yr and 2 yrs

Van der Kooji, metanalysis of 4 RCT: 27% at 5 yrs require hysterectomy

5 pregnancies and 5 live births after myomectomy
9 pregnancies and 6 live births after UAE


Hysterectomy for Uterine Fibroids.


Fertility and Pregnancy: 2010 meta-analysis of 227 pregnancies s/p UAE

UAE associated w/ higher miscarriage/TOP rates (64% vs 23%) vs myomectomy (29% vs 24%

Higher miscarriage rate: 35 vs. 17%, OR 2.8 (2.0-3.8)

Higher rate of postpartum hemorrhage: 14 vs 3%, OR 6.5 (3.5-11.7)

- Lacked power to detect difference in these outcomes

- No consistent between-group differences in the levels of biomarkers (FSH, LH, AMH) of ovarian reserve

- No difference in preterm delivery rates, IUGR, malpresentation

- Higher rate of postpartum hemorrhage: 14 vs 3%, OR 6.5 (3.5-11.7)

- Higher miscarriage rate :  35 vs. 17%, OR 2.8 (2.0-3.8)

- More commonly have C/S delivery: 66 vs 49%, OR 2.1 (1.4-2.9)

- Fertility

EMMY Trial (2016)

- Multi-center RCT (n = 254)
- Health-related QoL, patient satisfaction, menstrual bleeding scores, re-intervention rates
- At 6 weeks, then extended follow-up to 2, 5 and 10 years post-operatively

- Compared to baseline, QoL outcomes improved with no difference between groups

- Some effect seen at 2, 5, and 10 years
- At 10 years, 10% reported satisfaction from UAE, 67% satisfied with hysterectomy

- For UAE group, cumulative hysterectomy rates:
  - 4% at 2 years, 26% at 5 years and 42% at 10 years

- UAE vs Myomectomy

- No difference in re-intervention rates, nausea, vomiting, postoperative complications
- No difference in preterm delivery rates, IUGR, malpresentation
- Higher rate of postpartum hemorrhage: 14 vs 3%, OR 6.5 (3.5-11.7)

- No difference in the levels of biomarkers (FSH, LH, AMH) of ovarian reserve

- No consistent between-group differences in the levels of biomarkers (FSH, LH, AMH) of ovarian reserve

- Analysis at 6 weeks, then extended follow-up to 2, 5 and 10 years post-operatively

- No difference* in preterm delivery rates, IUGR, malpresentation

- Higher rate of postpartum hemorrhage: 14 vs 3%, OR 6.5 (3.5-11.7)

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- Pregnancy: 2010 meta-analysis of 227 pregnancies s/p UAE

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- Reproductive Outcomes after UAE

Volumetric Image-Guided Radiofrequency Fibroid Ablation (RFA)

- RFA utilizes low voltage, high frequency (450-500 kHz) alternating current to heat fibroid through needle electrodes

- Heat falls off with distance from electrode (1/d^4)

- Causes intracellular ions to oscillate generating frictional heat -> goal temperature 95'C

- Like other electrosurgical loops, current flows through body to dispersive pad and then returns to generator

- Caused by thermal energy @ 95-100'C and coagulative necrosis

- Prognostic factors
  - Menstrual bleeding scores were similar between groups

- No difference in perioperative and postoperative complication rates between groups

- Additional procedure performed
  - 7% (myomectomy) compared to 10% (UAE)

- Strengths
  - Racial diversity
  - Assessed fertility outcomes
  - 5 pregnancies and 5 live births after UAE
  - 9 pregnancies and 6 live births after myomectomy

- No consistent between-group differences in the levels of biomarkers (FSH, LH, AMH) of ovarian reserve

- Analysis at 6 weeks, then extended follow-up to 2, 5 and 10 years post-operatively

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- More commonly have C/S delivery: 66 vs 49%, OR 2.1 (1.4-2.9)
Bradley et al. 2019: Meta-analysis of 1300 subjects
Lin et al. 2019: Meta-analysis of 518 subjects
- Mean return to work: 5.1 days
- Fibroid volume reduction: 32-66% at 12 mo, 77% at >12 mo
- Re-intervention rates: 4.2%, 8.2%, 11.5%
- @ 3 years, 11% lap myomectomy, 17% UAE, 26% EM Ablation
- Statistically and clinically significant improvements in HRQOL, SSS up to 36 mo s/p treatment
- Complications not systematically collected but no reported deaths, visceral injuries

AAGL Practice Committee: examining laparoscopic, transvaginal, percutaneous, +/- image guided
- Outcomes considered: OR time, complications, fibroid volume reduction, HRQOL, menstrual bleeding, re-interventions, reproductive outcomes

RFA: Fibroid Volume Reduction Over Time

Aggregated transcervical and transabdominal RFA outcomes

Lap-RFA can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited availability data on reproductive outcomes

Berman et al. Case series from 2010 to 2017 using data from 2 RCT, 6 cohort studies, and commercial settings
- across multiple sites (such as university and community hospitals, and stand-alone surgery centers) in the US, Canada, Europe and Latin America
- 28 women had 30 resultant pregnancies s/p Lap RFA
- 26 full term live births (both C/S and SVD)
- 4 (13%) sabs
- No preterm deliveries, uterine rupture, placental abruption, placenta accrete or intrauterine growth restriction were reported
- 1 placenta previa, 1 post partum hemorrhage
- Based on a very limited case series, data suggest that safe childbearing with full term gestation is possible following the Lap RFA
- Follow up of LUSTOR Study (Dr. Sara Brucker, Tubingen, Germany)
- RCT lap RFA vs Lap Myomectomy
- 20 women treated w/ Lap RFA -> 7 women w/ 8 pregnancies, 1 sab -> 35% clinical pregnancy rate

RFA: Reproductive Outcomes

Equipment needed
- ProVu System
- 5 mm trocar
- 11 mm trocar
- 15 mm trocar
- Uterine manipulator

Discuss steps of the procedure
- Review Outcomes and Expectations

Acessa ProVu System
Acessa Procedural Steps

**PROCEDURE STEPS**

1. **Laparoscopic access**
   - 5mm camera, 10mm for ultrasound
2. **Laparoscopic survey and Map fibroids with ultrasound**
   - Identify endometrial cavity
3. **Insert handpiece (3mm) percutaneously parallel to ultrasound array**
4. **Target fibroids, Deploy array, treat fibroid**
   - Withdraw handpiece with monopolar cautery of track

Postoperative Expectations

- **Fibroid volume reduction by 40%**
  - Volume: \( V \) in \( \text{cm}^3 \)
  - Example: 5.6 cm \( \text{fibroid}\) \( \times \) 8.8 cm \( \text{fibroid} \) = 4.4 cm \( \text{fibroid} \)
- **Contraceptive change**
- **Recovery time and activities within 1 week**
  - By 2 months, notice decrease in uterine pressure and/or size, bleeding
  - **SSS decreased from 61.1 to 58.3**
  - First 1-2 periods may be irregular or heavy
  - By month 3, decreased menstrual bleeding (33% change in atrophic hysterection)
- By 3-6 months, decreased menarche at bleeding, SSS continues to decrease, HRQOL improves
- 3-month outcomes are predictive of 2-year outcomes

Sonata System

- **Sonata System**
  - Treatment device:
    - 8.3mm tip diameter (27 Fr)
  - Includes both intrauterine US and RF device
  - RF generator (<150W) to keep tip temperature at 105°C
  - Targeting software overlays on image
  - Ablates up to 5x4 cm area (can overlap)
  - 1-7 minute ablation times

Transcervical Fibroid Ablation

- In US, Sonata System only currently available FDA approved device
- "Incisionless" through the cervix
- "Safety and effectiveness with regard to fertility and fecundity after the use of the Sonata System have not been established, and effectiveness in women with clinically significant adenomyosis has not been established."
- Some in-office procedures, though at this time, most cases done in OR
The Sonata Procedure: Video

Sonata Outcomes

- Chudnoff et al. 12 months follow up
  - 127 patients completed 12 month fix (404 fibroids: 0.7-9 cm diameter)
  - 62% mean reduction in fibroid volume; 12.9% reduction in uterine volume
  - 95.1% reported reduction in menstrual bleeding
  - 40.2% experienced 50% reduction from their baseline flow
  - 94% satisfied, improved HRQL 41.2 points
  - 2 major adverse events: pelvic abscess @ 5 wks, 2 cm sigmoid serosal laceration intraoperatively by probe

- Berman et al. 36 month follow up
  - 127 pts at baseline -> 107 pts at 36 months
  - <1% reintervention at 12 months
  - 11% reintervention rate at 36 months
  - 50% due to undiagnosed adenomyosis

Sonata Outcomes

- OPEN Clinical Trial: 37 patients @ 6 sites
  - Mean fibroid diameter 3.2 ± 1.6 cm (range 1-8 cm)
  - 2nd look in 35 pts who underwent f/u hysteroscopy
  - 1 patient video was unevaluable (no agreement in evaluation by any of the 3 independent readers)
  - 34 showed no sign of adhesions after Sonata per agreement in evaluation by 2 independent readers
  - 6 out of 34 patients had apposing submucous fibroids ablated with no resulting adhesions

Sonata Outcomes

- RF ablation: Where we need more information
  - Fertility and pregnancy outcomes
    - Pregnancy rates
    - Live births
    - Conceptions
    - Longer term outcomes
  - Outcomes from concurrent procedures such as hysteroscopic myomectomy + RF ablation
  - Outcomes in patients with adenomyosis

Postoperative Expectations

- Similar recovery from hysteroscopy
  - Pain management w/ NSAIDs
  - More than 50% returned to usual activity in 1 day, mean 3.6 ± 2.2 days
  - Return to work mean 3.6 ± 2.2 days postprocedure
  - Early signs of amenorrhea vs amenorrhea
  - Symptomatic pts may confuse this procedure w/ endometrial ablation
  - Clinically meaningful improvement in HMB by 3 mo (39% reduction)
  - Possible intermenstrual spotting (sloughing)

Fertility and pregnancy outcomes

- Pregnancy rates
  - Live births
  - Conceptions
  - Longer term outcomes
  - Outcomes from concurrent procedures such as RF ablation and hysterectomy

Outcomes in patients with adenomyosis

Thank you!

Questions/Comments?

Kimberly.kho@utsouthwestern.edu

KimberlyKho1
RF Fibroid Ablation – So how does this work?

Craig J. Sobolewski, M.D.
Chief, Division of Minimally Invasive Gynecologic Surgery
Duke University

Disclosures
- Medtronic - Consultant and Speakers Bureau
- Cooper Surgical - Speakers Bureau
- Hologic - Paid Proctor

Objectives
- Describe the original techniques and outcomes of fibroid myolysis procedures
- Explain the technique and outcomes of laparoscopic volumetric radiofrequency ablation and transcervical fibroid ablation
- Explain the technique and outcomes of transcervical fibroid ablation

Myolysis
Noun | my-ol-y-sis |
Destruction or disintegration of muscle tissue

Not a new concept
- First performed in Hamburg, Germany by Gallinat and in Paris, France by Menqu in the late 1980’s
  - Presented at the ESGE meeting in 1990
- Technique involved drilling into the myoma using a bare Nd:YAG laser fiber under laparoscopic guidance
  - Multiple punctures 5-7 mm apart

Not a new concept
- Circumferential technique described by Goldfarb in 1995
  - Developed a 30 cm bipolar instrument using 50-75W applied until “cyanosis of the myoma is achieved”
  - Technique modified to use angular punctures to target the base of the myoma to “devascularize” it

Results of early procedures

- Myolysis using the Nd:YAG laser
  - Appeared to be safe
  - No transfusions or conversions in series of 48 patients
  - 41% mean reduction in diameter at 6 months and 1 year
  - 2nd look laparoscopy at 6 months (n=15) showed dense adhesions in 53%

- Myolysis using bipolar needles
  - Typically pre-treated with 12 weeks of GnRH agonist
  - 77% mean reduction of total uterine volume at 7-12 months (n=167)
  - Less adhesions noted at 2nd look
    - Mean score 1.15 ± 0.6 out of max of 11 (n=19)

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**Laparoscopic Radiofrequency Volumetric Tissue Ablation (RFVTA)**

- First described by Lee in 2002
- RFA utilizes a low voltage, high frequency (460-500kHz) alternating current transmitted to fibroid tissue through a needle electrode(s)
- Elevated temperatures are created to cause tissue destruction
  - Heat is created via ionic friction and then spreads by conduction
  - Cellular death occurs at 60 degrees Centigrade

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**Acessa RFVTA**

- FDA approved in 2012
- Mechanism of tissue destruction
  - RFA → Hypoxia → Dehydrates Cell & Denatures Proteins
  - Coagulative necrosis
  - Mass reduced by fragmentation and phagocytosis
- Ablation Volume
  - Determined by temperature as well as the duration of time at given temperature
  - Needle probe characteristics
    - Size, shape, number of electrodes
  - Target tissue characteristics
    - Heat sinks, scarring, heterogeneity
- ProVue targeting system
  - overlays ablation zone on ultrasound

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**Acessa Pivotal Trial**

- Prospective trial of 137 subjects with AUB-L
  - Excluded FIGO type 0 fibroids and MRI evidence of adenomyosis
  - Primary endpoints were menstrual blood reduction, reintervention at 12 months, adverse procedure events
    - Blood loss decreased by at least 50% in 40.2% of pts
    - One re-intervention for persistent AUB
    - One serious adverse event
  - Secondary endpoints were uterine volume reduction, UFS-QoL, and general health scores at 12 months
    - Volume decreased by 24.7%
    - Symptom severity score improved by 56% at 12 months
    - Health related QoL improved by 53% at 12 months

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References:
Transcervical Fibroid Ablation (TFA)

TFA

- First described by Cho, et al in 2008
- Utilized RFA needle placed under transabdominal or transrectal ultrasound guidance
- 91% reduction in symptoms and 46% improvement in QoL
- Garza-Leal, et al first described transcervical ablation system that incorporated intrauterine ultrasound in 2011

Sonata

- FDA approved in 2018
- System features
  - 8.3 mm tip diameter (27 Fr)
  - Articulating ultrasound tip
  - Infuse ~10 of hypotonic fluid for ultrasound coupling
  - Two ellipsoid treatment overlays
    - Inner ablation zone
    - Outer thermal safety border

Sonata Procedure Animation

Sonata Pivotal Trial

- Prospective trial of 147 subjects with AUB-L
  - Excluded FIGO type 0 fibroids > 1 cm, large or multiple polyps, and adenomyosis
  - Primary endpoints were menstrual blood reduction, and reintervention at 12 months
    - Blood loss decreased by at least 50% in 64.8% of pts
    - One re-intervention for persistent AUB
    - One serious adverse event
  - Secondary endpoints were uterine volume reduction, UFS-QoL and general health scores at 12 months
    - Volume decreased by 24.7%
    - Symptom severity score improved by 32.1 points at 12 months
    - Health related QoL improved by 43.7 points at 12 months

Summary

- Both transabdominal and transcervical ultrasound-guided radiofrequency ablation of leiomyomata are safe and effective uterine sparing options for the symptomatic relief of uterine fibroids
References

The Innovation of Technology in Fibroid Management
How Do We Integrate It Into Our Practices?

Jessica Shepherd MD, MBA, FACOG
Sanctum Med + Wellness
Baylor University Medical Center
Dallas, TX
Minimally Invasive Gynecology

Objectives

• Review the technology of Radiofrequency Ablation of Fibroids
• Discuss this newer interventional modality and how to incorporate it into practice
• Discuss patients concerns and considerations

ACOG featured panel for 2019

• A century ago, hysterectomy was the only widely available option for women with uterine fibroids, but today we have many minimally invasive procedures that are very effective and have good recovery profiles.
• Surgical alternatives to hysterectomy appear to be under-used, which makes this session an important opportunity to highlight those alternatives.
• The data across the United States, 75 percent of fibroid surgeries are hysterectomies. While there’s a place for hysterectomy, there are still many more women that can have an effective surgical alternative to hysterectomy.

Minimally Invasive Options for Fibroids

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Uterine Artery Embolization (UAE)</th>
<th>MRgFUS</th>
<th>Hysteroscopic Myomectomy (i.e., Myosure)</th>
<th>Transcervical RFA (Sonata, Gynesonics)</th>
<th>Endometrial Ablation (i.e., Novasure)</th>
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<tbody>
<tr>
<td>Visualize Scope + Ultrasound</td>
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<td>Lap. RFA (Acessa)</td>
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• Hysterectomy is the 2nd most common women’s surgery after C-Section
• Patients are often only offered hysterectomy for their fibroids
• Fibroids is a public health issue that is often overlooked
• Fibroid risk is 2-3x higher in African American women vs. in white women
• African American women who underwent hysterectomies, were 40% more likely to develop complications, nearly 3X as likely to have a long hospital stay, and 3X as likely to die

The potential to impact women’s health...

Disclosures

• Consultant: Hologic, Myovant, AbbVie, Acessa Health, for; Abbvie, Acessa Health, and Cynosure

• Review the technology of Radiofrequency Ablation of Fibroids
• Discuss this newer interventional modality and how to incorporate it into practice
• Discuss patients concerns and considerations

Objectives

Minimally Invasive Options for Fibroids

• Hysterectomy
• Myomectomy
• Lap. RFA (Acessa)
• Lap. Hysterectomy
• Uterine Artery Embolization (UAE)
• MRgFUS
• Hysteroscopic Myomectomy (i.e., Myosure)
• Transcervical RFA (Sonata, Gynesonics)
• Endometrial Ablation (i.e., Novasure)

Procedure Comparison

Capacity, Access is into ovary vs. standard of care (hysterectomy/myomectomy), more comprehensive than transcervical

• Acessa’s ultrasound is proven to identify 1.5x – 2.0x fibroids than TVUS and MRI
• Acessa addresses both bleeding and bulk

ACOG featured panel for 2019

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• Surgical alternatives to hysterectomy appear to be under-used, which makes this session an important opportunity to highlight those alternatives.
• The data across the United States, 75 percent of fibroid surgeries are hysterectomies. While there’s a place for hysterectomy, there are still many more women that can have an effective surgical alternative to hysterectomy.

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• Hysterectomy is the 2nd most common women’s surgery after C-Section
• Patients are often only offered hysterectomy for their fibroids
• Fibroids is a public health issue that is often overlooked
• Fibroid risk is 2-3x higher in African American women vs. in white women
• African American women who underwent hysterectomies, were 40% more likely to develop complications, nearly 3X as likely to have a long hospital stay, and 3X as likely to die

The potential to impact women’s health...

Disclosures

• Consultant: Hologic, Myovant, AbbVie, Acessa Health, for; Abbvie, Acessa Health, and Cynosure

• Review the technology of Radiofrequency Ablation of Fibroids
• Discuss this newer interventional modality and how to incorporate it into practice
• Discuss patients concerns and considerations

Objectives

Minimally Invasive Options for Fibroids

• Hysterectomy
• Myomectomy
• Lap. RFA (Acessa)
• Lap. Hysterectomy
• Uterine Artery Embolization (UAE)
• MRgFUS
• Hysteroscopic Myomectomy (i.e., Myosure)
• Transcervical RFA (Sonata, Gynesonics)
• Endometrial Ablation (i.e., Novasure)

Procedure Comparison

Capacity, Access is into ovary vs. standard of care (hysterectomy/myomectomy), more comprehensive than transcervical

• Acessa’s ultrasound is proven to identify 1.5x – 2.0x fibroids than TVUS and MRI
• Acessa addresses both bleeding and bulk

ACOG featured panel for 2019

• A century ago, hysterectomy was the only widely available option for women with uterine fibroids, but today we have many minimally invasive procedures that are very effective and have good recovery profiles.
• Surgical alternatives to hysterectomy appear to be under-used, which makes this session an important opportunity to highlight those alternatives.
• The data across the United States, 75 percent of fibroid surgeries are hysterectomies. While there’s a place for hysterectomy, there are still many more women that can have an effective surgical alternative to hysterectomy.

Minimally Invasive Options for Fibroids

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ACOG Practice Bulletin #228 (2021): Management of Symptomatic Uterine Fibroids

"Radiofrequency ablation (RFA) can be delivered by a laparoscopic, transvaginal, or transcervical approach... All of the approaches are similarly effective..."

"...RFA is a reasonable option to consider for the treatment of symptomatic uterine leiomyomas..."

This support comes within up to 9 years of commercialization of RF systems in the US in the GYN space.

Radiofrequency Relevance

- Minimally invasive
- Uterine-sparing
- Outpatient
- Rapid recovery
- No narcotics required
- Easy to use

Fibroid Treatment Alternative

- Improved symptoms
- Low complication rate
- Low re-intervention rate
- Identifies 2x the number of fibroids
- 98% of patients recommend it to friends
- 94% expressed satisfaction

Clinically Studied

- Faster time to normal activity
- No uterine incisions
- No morcellation

Fibroid Treatment Alternative

- Sonata System Hardware and Software
  - No manual measurements - all done graphically
  - Scalable ablations up to 4.9 cm x 4.2 cm
  - 1 to 7-minute ablation times
  - RF generator modulates power (≤ 150W) to keep electrode tip temperatures ~105°C

- Sonata Treatment Device
  - Combines intrauterine ultrasound with delivery of RF energy
  - 8.3 mm tip diameter (27 Fr dilatation)

**Procedure Overview**

1. • 5mm trocar for laparoscope inserted at umbilicus
   • 10mm trocar for laparoscopic ultrasound inserted at level of fundus
   • 3mm Acessa ProVu handpiece inserted within 3 fingerbreadths of ultrasound trocar parallel and in-plane with the direction of the ultrasound scan

2. • Under both laparoscopic guidance and ultrasound, the electrode array is deployed, confirmed in fibroid, and treatment completed

3. • Electrode array is retracted, Handpiece removed with monopolar coagulation, other fibroids may now be treated

4. • The fibroids are resorbed by the body over time

**Sonata System Technology**

- Sonata System Hardware and Software
  - No manual measurements - all done graphically
  - Scalable ablations up to 4.9 cm x 4.2 cm
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- Sonata Treatment Device
  - Combines intrauterine ultrasound with delivery of RF energy
  - 8.3 mm tip diameter (27 Fr dilatation)
Perks to the Surgeon

- Same Day Procedure
- Quick Recovery
- Minimal Pain Meds Post Op
- Can be done with concomitant procedures such as:
  - Hysteroscopic Myomectomy
  - Endometrial Ablation
  - Bilateral Salpingectomy
- Creates a Niche Practice Set up
- Reimbursement Plus

Standalone or Concomitant Treatment

Acessa can be used as a standalone treatment for most patients (type 1 – 6)

Patients who present with mixed pathology may receive adjunctive treatment

- Acessa + hysteroscopic morcellation (type 0)
- Acessa + myomectomy type (1-7)
- Acessa + endometriosis, adenomyosis, oophorectomy, etc.
- 12.5% of Acessa cases received adjunctive treatment

Procedure Overview

TFA Treats a Wide Range of Fibroid Types and Sizes

The Sonata System is designed to ablate or partially ablate any non-pedunculated uterine fibroid types in the FIGO Leiomyoma Subclassification System.

12-Month Results

- Menstrual blood loss reduction was clinically and statistically significant: 104 mL (alkaline hematin assessment) [p < .001]
- Fibroid volume decreased significantly by 44% [p < .001]
- Uterine volume decreased significantly by 25% [p < .001]
- 82% of women had lighter periods
- Half of patients experienced reduction in bleeding of > 40%
- One serious adverse event

IDE Study Results: ↓ of MBL, Fibroid Volume and Uterine Volume

Pre-Market IDE Study (n=135)

- Size, location & number ≤ 10cm, type 1-6 and an avg. 5/patient (2-29) fibroids
- Symptoms: Included women with bleeding and bulk
- Measuring tool for blood loss reduction - Alkaline Hematin

x

IDE Study Results: Sustained Improvements Out to 3 Years * for Acessa

- 3, 6, 12, 24 and 36 Month Results
  - Significant symptom reduction and health improvements sustained at 36 months.
  - <1% re-intervention at 12 months
  - <5%-6% re-intervention at 24 and 36 months
  - 11% cumulative re-intervention at 36 months
  - 3-month results indicative of 36-month results

IDE Summary

- A durable treatment out to 3 years
- Reduced blood loss, symptoms and fibroid size
- Improved quality of life

Significant Quality of Life Improvements Persist Through 3 Years for Sonata

- Mean Symptom Severity Score (SSS) and Health Related Quality of Life (HR-QoL) Outcomes
  - Sustained improvements through 3 years
  - All p-values <0.001 compared to baseline
LUSTOR Study Results: Hospitalization, Intraop Blood Loss, Fibroids and Symptoms*

Randomized Study – Acessa vs. Laparoscopic Myomectomy (n=50)

- **Acessa**
  - Significantly shorter hospitalization time
  - Significantly lower intraoperative blood loss
  - More fibroids treated by Acessa than excised by LM as a percentage of those imaged during surgeries

- **Acessa & Laparoscopic Myomectomy**
  - Improved Symptom Severity
  - Improved Health-Related Quality of Life
  - Improved Health State Scores (EQ-5D)

**Other Qualitative Acessa**
- Fewer days missed from work
- Faster time to normal activity
- No uterine incisions
- No morcellation

**Acessa & Laparoscopic Myomectomy**
- Improved Symptom Severity
- Improved Health-Related Quality of Life
- Improved Health State Scores (EQ-5D)

**LUSTOR Study Results**

- **Hospitalization, Intraop Blood Loss, Fibroids and Symptoms**

**10 Year Meta-Analysis**

- **Weighted average reintervention rates**
  - Myomectomy: 4.2% (f/u = 34.7 months)
  - Lap-RFA: 5.2% (f/u = 27.0 months)
  - UAE: 14.8% (f/u = 13.5 months)
  - MRgFUS: 30.5% (f/u = 12.6 months)
  - TFA: 8.2% (f/u = 36 months)

- **Readmission rates within 90 days of discharge**
  - Lap-RFA: 0.7%
  - Myomectomy: 2.7%
  - UAE: 3.4%
  - MRgFUS: 7.4%

**References**

CULTURAL AND LINGUISTIC COMPETENCY

Assembly Bill 1195 was signed into law on July 1, 2006 requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP). It is the intent of the Legislature to encourage physicians and surgeons, continuing medical education providers located in California, and the Accreditation Council for Continuing Medical Education to meet the cultural and linguistic concerns of a diverse patient population through appropriate professional development.

Linguistic Competence: Providing readily available, culturally appropriate oral and written language services to limited English proficiency (LEP) members through such means as bilingual/bicultural staff, trained medical interpreters, and qualified translators.

Cultural Competence: A set of congruent behaviors, attitudes, and policies that come together in a system or agency or among professionals that enables effective interactions in a cross-cultural framework.

Cultural and Linguistic Competence: The ability of health care providers and health care organizations to understand and respond effectively to the cultural and linguistic needs brought by the patient to the health care encounter.

Cultural competence requires organizations and their personnel to:

• Value diversity.
• Assess themselves.
• Manage the dynamics of difference.
• Acquire and institutionalize cultural knowledge.
• Adapt to diversity and the cultural contexts of individuals and communities served.

California Business & Professions Code §2190.1(c)(3) states that associations that accredit continuing medical education courses shall develop standards before July 1, 2006, for compliance with the cultural competency requirements. The associations may update these standards, as needed, in conjunction with an advisory group that has expertise in cultural and linguistic competency issues. Cultural competency means a set of integrated attitudes, knowledge, and skills that enables a health care professional or organization to care effectively for patients from diverse cultures, groups, and communities. At a minimum, cultural competency is recommended to include the following: (A) Applying linguistic skills to communicate effectively with the target population. (B) Utilizing cultural information to establish therapeutic relationships. (C) Eliciting and incorporating pertinent cultural data in diagnosis and treatment. (D) Understanding and applying cultural and ethnic data to the process of clinical care, including, as appropriate, information pertinent to the appropriate treatment of, and provision of care to, the lesbian, gay, bisexual, transgender, and intersex communities.

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 http://www.usdoj.gov/crt/cor/pubs.htm.

Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”, signed by the President on August 11, 2000 http://www.usdoj.gov/crt/cor/13166.htm was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

Dymally-Alatorre Bilingual Services Act (Assembly Bill 305) requires that state agencies that serve a substantial number of non-English-speaking people employ a sufficient amount of bilingual persons in order to provide certain information and render certain services in a language other than English.