Plenary 3: Hysteroscopy

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Plenary 3: Hysteroscopy

Moderator: Rafael F. Valle
Co-Moderators: Philip G. Brooks, Eylon Lachman

Faculty: Howard L. Curlin, Stephanie Jost, Josien P.M. Penninx, Shannon E. Smith, Grace W. Yeung

Course Description

This session on “Hysteroscopy” will include 5 presentations, 4 related to endometrial ablation (EA) and 1 related to tubal sterilization. In the 4 presentations dealing with EA, the role of adenomyosis in the outcome of the procedures shows that its presence does not increase the risk of hysterectomy, pain or abnormal bleeding. A comparison between Novasure and Thermablate notes a higher amenorrhea rate with the Novasure method. A review of pregnancies occurring after Novasure EA points to side effects such as IUGR, placenta accreta, and uterine rupture in those patients. Also the repeated resectoscopic EA seems feasible and safe in those patients who fail to respond to the first attempt. Finally, a large series of patients, over 2,500, sterilized with the Essure system with up to 5 years follow up; demonstrate the method’s safety and effectiveness performed under sedation.

Course Objectives

At the conclusion of this session, the participant will be able to: 1) Review the risk of adenomyosis in the outcome of endometrial ablation; 2) review the risks involved in pregnancies following endometrial ablation; and 3) review various methods for successful placement of Essure devices from the analysis of a large population of women sterilized with this method.

Course Outline

2:15  The Association between the Diagnosis of Adenomyosis by Pelvic Ultrasound Prior to Endometrial Ablation and the Subsequent Risk of Hysterectomy  H.L. Curlin
2:25  Pregnancy Outcomes Following a NovaSure®Endometrial Ablation Procedure  S.E. Smith
2:35  Bipolar Radiofrequency Endometrial Ablation Versus Thermablate Balloon Ablation for Dysfunctional Bleeding in the Outpatient Clinic: A Randomized Controlled Trial  J.P.M. Penninx
2:45  Repeat Resectoscopic Endometrial Resection after Failed Primary Resectoscopic Endometrial Ablation: Is It Worth the Risk?  G.W. Yeung
2:55  ESSURE® Implants for Tubal Sterilisation in France – Hysteroscopic Tubal Sterilisation: French Multicentre Cohort Study SUCCES II  S. Jost
3:05  Discussion
3:15  Adjourn
PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop and have no conflict of interest to disclose (in alphabetical order by last name).
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Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
Jonathan Solnik
Other: Lecturer - Olympus, Lecturer - Karl Storz Endoscopy-America

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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).
Howard L. Curlin*
Shannon E. Smith*
Josien P.M. Penninx*
Grace Yeung*
Stephanie Jost*
Rafael F. Valle*
Eylon Lachman*
Philip G. Brooks
Consultant: Boston Scientific Corp. Inc.

Asterisk (*) denotes no financial relationships to disclose.
THE ASSOCIATION BETWEEN THE DIAGNOSIS OF ADENOMYOSIS BY PELVIC ULTRASOUND PRIOR TO ENDOMETRIAL ABLATION AND THE SUBSEQUENT RISK OF HISTERECTOMY

Howard Curlin, MD
May Thomassee, MD, Amanda Yunker, DO, MSCR, Ted Anderson, MD, PhD
Madigan Healthcare System and Vanderbilt University Medical Center

Disclosures

- The views expressed are those of the author(s) and do not reflect the official policy of the Department of the Army, the Department of Defense or the U.S. Government.
- I have no financial relationships to disclose

Educational Objectives

- At the end of this presentation the participant will be able to describe the methods used to diagnose adenomyosis and the limitations in making the diagnosis
- The participant will be able to list the reported impact of adenomyosis on endometrial ablation

Background

- Up to 30% of women will have a hysterectomy within 4 yrs of endometrial ablation (1)
- Predictors of treatment failure after endometrial ablation (2-5)
  - Age <40-45
  - Parity >4
  - History of dysmenorrhea
  - Tubal ligation
  - Type of ablation

Historically histologic evaluation was the only practical way to diagnose suspected adenomyosis
- Both ultrasound and magnetic resonance imaging (MRI) have been reported to be reliable for diagnosing adenomyosis (6,7)
  - Ultrasound: positive likelihood ratio 3.7-4.7
  - MRI: positive likelihood ratio 6.5

Adenomyosis as a risk factor for failure of endometrial ablation (8-11)
- Persistent or recurrent abnormal bleeding
- Pain
- Need for subsequent hysterectomy
Objective

- To analyze whether patients with a preoperative pelvic ultrasound diagnosis of adenomyosis are at increased risk of ablation failure and subsequent hysterectomy

Methods

- Vanderbilt University Medical Center
- Retrospective Cohort
  - Mean follow-up of 2.4 years
  - Identified patients who underwent endometrial ablation via ICD codes
    - January 2006 through September 2010
    - 437 patients

CHART ABSTRACTION

- Age at ablation
- Parity
- BMI
- Number of prior cesarean sections
- Smoking status
- History of endometriosis
- History of dysmenorrhea
- Presence of anemia

- Presence of fibroids
- Presence of an endometrial polyp
- Bilateral tubal ligation
- Prior myomectomy
- Uterine size
- Endometrial hyperplasia at time of ablation

Demographics

<table>
<thead>
<tr>
<th>Patient Demographic</th>
<th>No adenomyosis on US Mean or % (n=310)</th>
<th>Adenomyosis on US Mean or % (n=127)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at ablation (yr)</td>
<td>41.8</td>
<td>41.9</td>
<td>NS</td>
</tr>
<tr>
<td>Parity</td>
<td>1.9</td>
<td>2.2</td>
<td>NS</td>
</tr>
<tr>
<td>BMI</td>
<td>30.7</td>
<td>30.3</td>
<td>NS</td>
</tr>
<tr>
<td># of prior c-sections</td>
<td>1.3</td>
<td>1.3</td>
<td>NS</td>
</tr>
<tr>
<td>Uterine size [cm]</td>
<td>8.7</td>
<td>8.3</td>
<td>NS</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>7.1 %</td>
<td>4.8 %</td>
<td>NS</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>38.5 %</td>
<td>45.6 %</td>
<td>NS</td>
</tr>
<tr>
<td>Anemia</td>
<td>37.4 %</td>
<td>15.2 %</td>
<td>NS</td>
</tr>
<tr>
<td>Fibroids</td>
<td>41.0 %</td>
<td>31.8 %</td>
<td>NS</td>
</tr>
<tr>
<td>Endometrial polyp</td>
<td>10.7 %</td>
<td>12.0 %</td>
<td>NS</td>
</tr>
<tr>
<td>Bilateral tubal ligation</td>
<td>48.6 %</td>
<td>51.2 %</td>
<td>NS</td>
</tr>
<tr>
<td>Prior myomectomy</td>
<td>13.9 %</td>
<td>14.5 %</td>
<td>NS</td>
</tr>
<tr>
<td>Smoker</td>
<td>21.6 %</td>
<td>22.9 %</td>
<td>NS</td>
</tr>
<tr>
<td>Endometrial hyperplasia</td>
<td>14.4 %</td>
<td>10.8 %</td>
<td>NS</td>
</tr>
</tbody>
</table>

Results

- 29% of patients diagnosed preoperatively with adenomyosis by pelvic ultrasound

<table>
<thead>
<tr>
<th>Marker for failure</th>
<th>% with no adenomyosis (n=310)</th>
<th>% with adenomyosis (n=127)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysterectomy</td>
<td>11.2</td>
<td>17.1</td>
<td>.128</td>
</tr>
<tr>
<td>Posts-operative pain</td>
<td>16.8</td>
<td>22.3</td>
<td>.206</td>
</tr>
<tr>
<td>Post-ablation abnormal bleeding</td>
<td>19.2</td>
<td>19.8</td>
<td>.892</td>
</tr>
</tbody>
</table>

- 62 (14.2%) patients had subsequent hysterectomy

<table>
<thead>
<tr>
<th>Adenomyosis on US</th>
<th>No Adenomyosis on histology (n=36)</th>
<th>Adenomyosis on histology (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>31 (64.6%)</td>
<td>17 (73.9%)</td>
</tr>
<tr>
<td>Yes</td>
<td>7 (50.0%)</td>
<td>7 (50.0%)</td>
</tr>
</tbody>
</table>
Conclusions

- Establishing a pre-treatment diagnosis of adenomyosis by ultrasound can be elusive
  - Varied definitions and stringency by radiologists
  - Varied definitions and stringency by pathologists
- Our data suggest that adenomyosis diagnosed via pelvic ultrasound prior to endometrial ablation does not increase the risk of subsequent hysterectomy, pain, or abnormal bleeding
  * The subset of patients who went on to have hysterectomy had poor correlation between ultrasound and histologic diagnosis

References

Background

• While uncommon, pregnancy after endometrial ablation can occur.
• Post-ablation pregnancies may be complicated by significant morbidity and adverse maternal and fetal outcomes.
• Little is known about physician counseling on the use of a reliable form of birth control post-endometrial ablation.

Study Objectives

• To evaluate outcomes of pregnancies that occurred following radiofrequency endometrial ablation.
• To determine if contraceptive counseling was provided to women who became pregnant.

Subjects and Methods

• Survey of physicians who reported pregnancies following radiofrequency endometrial ablation
  – Hologic post-market quality assurance surveillance program
• 20 pregnancies were reported between March 2009 and April 2012
  – Physician follow-up was available for 6 patients
    • 5 pregnancies with outcomes data
    • 1 uncomplicated 3rd trimester pregnancy

Outcome Measures

• Patient demographics
• Birth control counseling and use
• Time from ablation to pregnancy
• Pregnancy outcomes
  – Termination
  – Delivery
    • Gestational age
  – Complications
    • Maternal
    • Fetal
Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>n=5</th>
<th>±</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>33.2</td>
<td>± 5.5</td>
</tr>
<tr>
<td>Pregnancy history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gravidity</td>
<td>5.2</td>
<td>± 3.2</td>
</tr>
<tr>
<td>Parity</td>
<td>3.2</td>
<td>± 1.6</td>
</tr>
<tr>
<td>Received contraceptive counseling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>(20%)</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>(60%)</td>
</tr>
<tr>
<td>Unsure</td>
<td>1</td>
<td>(20%)</td>
</tr>
<tr>
<td>Birth control used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>(100%)</td>
</tr>
<tr>
<td>Time between ablation – pregnancy, mo</td>
<td>18.6</td>
<td>± 9.2</td>
</tr>
</tbody>
</table>

Pregnancy Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>n=5</th>
<th>±</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous abortion, #</td>
<td>1</td>
<td>(20%)</td>
</tr>
<tr>
<td>Live births, #</td>
<td>4</td>
<td>(80%)</td>
</tr>
<tr>
<td>Delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Gestational age, time of delivery, wks</td>
<td>27 - 35</td>
<td></td>
</tr>
<tr>
<td>Complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pt 1 - IUGR, uterine rupture, cesarean hysterectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pt 2 - PPROM, placenta accreta, postpartum pyelonephritis with sepsis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pt 3 - Fetal distress/ decelerations, terminal bradycardia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pt 4 – IUGR, NRFHT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Pre-ablation pregnancy history

Conclusions

- Adverse maternal and fetal outcomes occurred in pregnancies that continued beyond the first trimester which is consistent with previous reports in the medical literature.
- These results emphasize the importance of physician counseling on the use of a reliable birth control method for patients undergoing endometrial ablation.
Novasure versus Thermablate in the outpatient clinic
a randomized controlled trial

Novasure

- Three dimensional bipolar ablation device
- Radiofrequency
- No hysteroscopy
- ± 90 seconds (max. 120 seconds)
- Controls the depth of the ablation

Thermablate

- Balloon endometrial ablation
- No hysteroscopy
- Fluid heated to 173 °C in 8 minutes
- Duration treatment: 2 minutes and 6 seconds

Objective Summary

- Significant higher amenorrhea rate in the Novasure group
- PCAS at 6 months significant lower
- Pain scores are equal in both groups
- Equal amount of re-interventions
- Satisfaction rates higher in Novasure group

Ambulant Setting

- NSAID (Naproxen) 1 hour before treatment
- (para)cervical block with ultracaine
- Start treatment after 2 minutes
- Naproxen 500mg, paracetamol 1000mg post treatment
- Tramal 100mg

Disclosure

- I have no financial relationships to disclose.
**Multicenter RCT; 3 Hospitals**

March 2009 until November 2011

**Power analysis:** 52 Novasure and Thermablate

**Inclusion criteria**
- Dysfunctional uterine bleeding
- Treatment in ambulant setting

**Exclusion criteria**
- Future pregnancy
- Uterine depth < 6 cm or > 12 cm
- Abnormal cervical cytology

**Primary outcome**
- Amenorrhea

**Secondary outcomes**
- Menstruation pattern
- VAS score
- Re-intervention
- Satisfaction

**Inclusion criteria**
- Menstruation pattern
- VAS score
- Re-intervention
- Satisfaction

**Measurement tools**
- Modified Higham Diary Score (PCAS)
- Visual analogue scale
- Patient satisfaction

**Patient unaware of treatment allocation until 1 year after treatment**

**Analysis performed by intention-to-treat**

**Preliminary results**

104 patients randomized

<table>
<thead>
<tr>
<th>51 Thermablate</th>
<th>3 Novasure</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months 38 patients</td>
<td>9 months 39 patients</td>
</tr>
<tr>
<td>12 months 34 patients</td>
<td></td>
</tr>
</tbody>
</table>

**Novasure group**

<table>
<thead>
<tr>
<th>Age</th>
<th>46</th>
<th>45</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictorial blood assessment score</td>
<td>992</td>
<td>988</td>
</tr>
<tr>
<td>Duration menstruation (days)</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Duration of clots</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td>Dysmenorrhea (%)</td>
<td>Mild</td>
<td>Severe</td>
</tr>
<tr>
<td>Hb (g/L)</td>
<td>8.2</td>
<td>5.6</td>
</tr>
<tr>
<td>MTH (IU/L)</td>
<td>9.8</td>
<td>5.7</td>
</tr>
</tbody>
</table>
**RESULTS - AMENORRHEA**

**Novasure vs Thermablate:**
- 6 months: 52% versus 19% RR 4.8 (95%CI 1.6-14)
- 12 months: 55% versus 12% RR 2.7 (95%CI 1.3-5.8)

**RESULTS - PCAS**

![Graph showing results for PCAS]

6 months: p = 0.010
12 months: p = 0.31

**RESULTS - VAS SCORE**

![Graph showing VAS score results]

**RESULTS - HYSTERECTOMY**

<table>
<thead>
<tr>
<th></th>
<th>Thermablate 6 months</th>
<th>Novasure 6 months</th>
<th>Thermablate 12 months</th>
<th>Novasure 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysterectomy</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

**RESULTS - SATISFACTION**

6 AND 12 MONTHS

![Graph showing satisfaction levels]
Repeat Resectoscopic Endometrial Ablation after Failed Resectoscopic Endometrial Ablation: Is it Worth the Risk?

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George A Vilos, MD²
Meivys Garcia-Erdeljan, MD³
Jennifer Marks, MD⁴
Angelos G Vilos, MD⁵
Basim Abu-Rafea, MD⁶

Department of Obstetrics and Gynecology, Western University, London, Canada¹⁻⁵, King Saud University, Riyadh, Saudi Arabia²⁻⁶

41st AAGL Global Congress on Minimally Invasive Gynecology

Disclosures

- I have no financial relationships to disclose.

Objectives

To describe:
1. Patient characteristics;
2. Uterine cavity and;
3. Clinical outcomes
of women who failed resectoscopic rollerball or loop endometrial ablation (REA) and subsequently consented to repeat resectoscopic endometrial ablation (RREA)

Background

- Resectoscopic endometrial ablation (REA) was introduced in the 1980s as an alternative to hysterectomy to treat abnormal uterine bleeding (AUB) from benign causes¹
- Following REA, long-term outcomes indicate that 15% to 30% of women require additional surgery such as repeat ablation or hysterectomy for persistent AUB, uterine/pelvic pain or both²
- Hysterectomy is a major surgical procedure associated with significant morbidity, mortality, and health care costs and resources³
- Consequently, we routinely offer repeat resectoscopic ablation (RREA) as an alternative to hysterectomy after failed ablation

Materials & Methods

- Design: Retrospective cohort (II-2)
- Setting: University-affiliated hospital
- Patients: 183 women who failed primary REA underwent RREA by the senior author (GAV) from 1993 to 2007 (5-yr follow up)
- Interventions: Medical record chart review
- Patient follow-up by office visits and telephone interview

Patient Demographics

<table>
<thead>
<tr>
<th>Table 2: Demographics of 183 women who underwent repeat resectoscopic endometrial ablation</th>
<th>Primary Ablation</th>
<th>Secondary Ablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), yr</td>
<td>43 (26-70)</td>
<td>43 (29-76)</td>
</tr>
<tr>
<td>Body Mass Index, median (range) kg/m²</td>
<td>25.3 (19.7-41.5)</td>
<td>25.3 (19.7-41.5)</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous, n (%)</td>
<td>19 (10.4)</td>
<td>19 (10.4)</td>
</tr>
<tr>
<td>Parous, n (%)</td>
<td>164 (89.6)</td>
<td>164 (89.6)</td>
</tr>
<tr>
<td>Mode of Delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cesarean Section, n (%)</td>
<td>36 (19.8)</td>
<td>36 (19.8)</td>
</tr>
<tr>
<td>Vaginal Delivery, n (%)</td>
<td>150 (71.3)</td>
<td>150 (71.3)</td>
</tr>
<tr>
<td>Type of Ablation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rollerball, n (%)</td>
<td>87 (47.5)</td>
<td>41 (22.4)</td>
</tr>
<tr>
<td>Resection, n (%)</td>
<td>62 (33.9)</td>
<td>136 (74.3)</td>
</tr>
<tr>
<td>Combined, n (%)</td>
<td>34 (18.6)</td>
<td>6 (3.3)</td>
</tr>
</tbody>
</table>
Concomitant Laparoscopy for Pain and/or Pelvic Mass

Table 1. Laparoscopic findings and procedures in 29 women who had concomitant laparoscopy for various indications at the time of Repeat Reversoscopic Endometrial Ablation

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometriosis</td>
<td>21</td>
</tr>
<tr>
<td>Hematosalpinx</td>
<td>3</td>
</tr>
<tr>
<td>Adhesions</td>
<td>9</td>
</tr>
</tbody>
</table>

Laparoscopic Procedures: Normal laparoscopy (22), Salpingoophorectomy (6), Lysis of adhesions (9), Bilateral salpingectomy (10), Appendectomy (1), Bilateral lysis of ovarian endometriomas, lysis of peritoneal adhesions (1).

Technique of Repeat Ablation

- All RREA were performed under general anesthesia
- 1.5% glycine irrigant solution
- 26 F resectoscope with an 8 mm monopolar loop electrode or 5mm rollerball:
  - Loop with 120 W low voltage (cut) waveform (74.3%)
  - Rollerball with high voltage (coag) waveform (22.4%)
  - Both (3.3%)

Indications for Primary Ablation

- AUB (86.9%)
- AUB & Dysmenorrhea/Pain (10.4%)
- Dysmenorrhea/Pain (1.1%)
- PMB (1.6%)

Indications for Secondary Ablation

- AUB (53.0%)
- AUB & Dysmenorrhea/Pain (26.2%)
- Dysmenorrhea/Pain (19.1%)
- PMB (1.1%)
- Ultrasonic Thickened Endometrium (0.5%)

Cavity Appearance at Repeat Ablation

- Cavity appeared distorted/absent in all cases:
  - Contracted
  - Endometrial pockets
  - No cavity
  - Septum-like
  - False passage
  - Stenotic
- Hysteroscopic findings:
  - Leiomyoma (17)
  - Hematometra (14)
  - Polyps (1)
Outcome of Second Ablation

Table 3. Follow-up of 158 (86%) Women after Repeat Resectoscopic Endometrial Ablation, median 9 years, (range 3-19)

| Procedure                              | n (%)
|----------------------------------------|------
| Hysterectomy                           | 49 (26.8)
| Third Resectoscopic Resection, n (%)   | 3 (1.6)
| Short-term Medical Therapy, n (%)      | 5 (2.7)
| Oral Contraceptive                     | 2    
| Oral Contraceptive, Lupron             | 1    
| Danazol                                | 1    
| Depo-provera                           | 1    

Indications for Hysterectomy

Table 4. Indications for Hysterectomy for 49 Women (26.8%) after Repeat Resectoscopic Endometrial Ablation, n (%)

| Indication             | n (%) | (
|------------------------|-------|------
| Hysterectomy           | 49 (26.8) |     
| Pain                   | 22 (44.9)  |     
| Bleeding               | 4 (8.16)    |     
| Pain and bleeding      | 17 (34.7)  |     
| Other                  | 6 (12.2)   |     

Patients Requiring No Treatment for Abnormal Uterine Bleeding

Table 5. Women requiring no further treatment after Repeat Resectoscopic Endometrial Ablation, n (%)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No Further Treatment</td>
<td>129 (70.5)</td>
<td></td>
</tr>
<tr>
<td>Amenorrheic</td>
<td>89 (73.5)</td>
<td></td>
</tr>
<tr>
<td>Perimenopausal</td>
<td>11 (9.5)</td>
<td></td>
</tr>
<tr>
<td>Menopausal</td>
<td>78 (64.5)</td>
<td></td>
</tr>
<tr>
<td>Deceased</td>
<td>2 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Cervical cancer, squamous cell, FIGO stage IIa</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Breast cancer, metastasis to brain and lung</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
Table 6. Complications of Repeat Rectoscopic Endometrial Ablation, n (%)  

<table>
<thead>
<tr>
<th>Complication</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation: Incomplete resection, laparoscopy performed, no injury, subsequent vaginal hysterectomy for pain, leiomyoma</td>
<td>1</td>
</tr>
<tr>
<td>Resection completed, subsequent abdominal hysterectomy for infection, no histopathology record</td>
<td>1</td>
</tr>
<tr>
<td>Failure Passage: Resection completed, subsequent vaginal hysterectomy for pain and hematomata, normal histopathology</td>
<td>1</td>
</tr>
<tr>
<td>Resection completed, lost to follow-up</td>
<td>1</td>
</tr>
<tr>
<td>Resection completed, subsequent abdominal hysterectomy for pain, hematomata and infection, adenomyosis</td>
<td>1</td>
</tr>
<tr>
<td>Excessive Bleeding: Emergency abdominal hysterectomy; adenomyosis and leiomyoma</td>
<td>1</td>
</tr>
<tr>
<td>Tamponade with Foley catheter balloon</td>
<td>1</td>
</tr>
<tr>
<td>Incomplete Resection: Ovaries, hematomata, lost to follow-up</td>
<td>1</td>
</tr>
<tr>
<td>Total Complications</td>
<td>8 (4.4)</td>
</tr>
</tbody>
</table>

**Conclusions**

- RREA obviates hysterectomy in 73.2% of women who fail primary REA
- RREA is a feasible, safe alternative to hysterectomy for AUB from benign causes when performed by experienced surgeons

**References**

“ESSURE® Implants for Tubal Sterilisation in France – Hysteroscopic Tubal Sterilisation: French Multicentre Cohort Study SUCCES II.”

S. JOST, M. P. PANEL, M.D. Centre Hospitalier de Versailles, France

41st Annual Global Congress, AAGL

Disclosure slide

I have no financial relationships to disclose.

Efasure™ procedure

- 1st procedure in 1998
- Approved in 2002 (FDA)
- More than 600,000 procedures worldwide
- More than 100,000 procedures in France
- In France: reimbursement since 2004

Succes II

- Prospective study
- Observational
- National
- Multicenter
- Start: September 1st 2008
- End of inclusions: May 2011
- Planned end of study: June 1st 2016

- Principal objective: Efficacy of the Essure™ implants in France.
- Secondary objectives: Predicting factors of placement failure, Predicting factors of pain during procedure, Satisfaction and regrets

Study Design

- Objective: >2,500 patients included
- 13 centers

Inclusion and exclusion criteria

Inclusion criteria:
- Patients seeking definitive birth control
- Written information
- 4-months reflection period
- Written consent form signed by each patient

Exclusion criteria:
- Active or recent upper or lower pelvic infection
- Known hypersensitivity to nickel as confirmed by skin test
- Pregnancy or suspected pregnancy
- Inability or refusal to provide informed consent
Results after 1st attempt

- 2,575 patients included
- 40 failure (withdrawal from procedure)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Success</th>
<th>Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2,866</td>
<td>109</td>
</tr>
<tr>
<td>Success</td>
<td>2,307</td>
<td>109</td>
</tr>
<tr>
<td>Failure</td>
<td>55</td>
<td>0.67%</td>
</tr>
<tr>
<td>Bilateral</td>
<td>55</td>
<td>2.00%</td>
</tr>
<tr>
<td>Unilateral</td>
<td>2,307</td>
<td>91%</td>
</tr>
</tbody>
</table>

Average child = 2.46
Standard deviation = 1.14
Median child = 2

Use of contraceptives

Before

n=2,593

After

n=1,695

Technique

- Duration: median = 5 min, average = 6.7 min +/- 4.9
- Used technique: 96% of Bettochi method
- Premedication: 86% (NSAID = 42.4%); combination with NSAID = 44.7%; non-NSAID = 12.8%
- Anaesthesia modalities
- Associated procedures:

<table>
<thead>
<tr>
<th>Associated procedure</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative hysteroscopy</td>
<td>44</td>
</tr>
<tr>
<td>Endometrectomy</td>
<td>38</td>
</tr>
<tr>
<td>Polyp ablation</td>
<td>20</td>
</tr>
<tr>
<td>Thermo-coagulation</td>
<td>25</td>
</tr>
<tr>
<td>Curettage</td>
<td>20</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>12</td>
</tr>
<tr>
<td>IUD ablation</td>
<td>139</td>
</tr>
<tr>
<td>Others (non-uterine procedure)</td>
<td>70</td>
</tr>
<tr>
<td>Total</td>
<td>375</td>
</tr>
</tbody>
</table>

3-months confirmation test

- 2,535 patients, 166 cases of discontinue of procedure
- 2,389 patients must have undergone confirmation test
- 2,149 patients did it i.e. 83.5%
- Rate of lost to follow-up: 9.3% (220/2369)

Delay: 109 days on average

Success rate at 3 months: 97.7%

Predictive factors of failure

- Pain (p<0.0001)
- Lack of ostia visualisation: 38 cases of withdrawal from procedure
- No premedication or insufficient premedication (without NSAID)
- Retroverted uterus
Pain

- Predictive factors:
  - Past tubal surgery
  - Endometriosis
  - Painful period
  - No use of analgesic
- Correlation between pain during period and pain during the procedure (double-correlation)

Satisfaction

- 2,575 patients
- 2,535 procedures in the end

Conclusion

- First large-scaled prospective study
- 2,575 patients all over France
- First results:
  - Low pain
  - Vaginoscopy++ Bettocchi’s method
  - High level of patients’ satisfaction
  - Importance of 3-months control

References

CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law AB 1195 (eff. 7/1/06) 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).

California Business & Professions Code §2190.1(c)(3) requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at http://www.imq.org

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 (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

~

If you add staff to assist with LEP patients, confirm their translation skills, not just their language skills. A 2007 Northern California study from Sutter Health confirmed that being bilingual does not guarantee competence as a medical interpreter. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2078538.