Plenary 3 – Hysteroscopy

MODERATORS
Linda D. Bradley, MD & Paul D. Indman, MD

Vinod Kumar, MD  Angie Y. Lee, MD  Mark D. Levie, MD
Ayman Oraif, MD  Brenda Sohn, MD  M.P.H. Vleugels, MD, PhD
Professional Education Information

Target Audience
This educational activity is developed to meet the needs of residents, fellows and new minimally invasive specialists in the field of gynecology.

Accreditation
AAGL is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The AAGL designates this live activity for a maximum of 1.0 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS
As a provider accredited by the Accreditation Council for Continuing Medical Education, AAGL must ensure balance, independence, and objectivity in all CME activities to promote improvements in health care and not proprietary interests of a commercial interest. The provider controls all decisions related to identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity. Course chairs, planning committee members, presenters, authors, moderators, panel members, and others in a position to control the content of this activity are required to disclose relevant financial relationships with commercial interests related to the subject matter of this educational activity. Learners are able to assess the potential for commercial bias in information when complete disclosure, resolution of conflicts of interest, and acknowledgment of commercial support are provided prior to the activity. Informed learners are the final safeguards in assuring that a CME activity is independent from commercial support. We believe this mechanism contributes to the transparency and accountability of CME.
# Table of Contents

Course Description ........................................................................................................................................ 1

Disclosure ...................................................................................................................................................... 2

Nickel Sensibilization after Essure Sterilization Non Item Anymore?
M.P.H. Vleugels ........................................................................................................................................... 3

A Prospective Study on Factors Important to Women Receiving Counseling about Tubal Sterilization and Their Impact on Ultimate Contraception Method Chosen
A.Y. Lee.......................................................................................................................................................... 6

Resectoscopic Rollerball Endometrial Ablation and Concomitant Levonorgestrel-Releasing Intrauterine System in Women with Abnormal Uterine Bleeding: Is the Combination Better?
B. Sohn .......................................................................................................................................................... 8

Long-Term Clinical Outcomes of Resectoscopic Endometrial Ablation in Women with Simple and Complex Endometrial Hyperplasia without Atypia and Abnormal Uterine Bleeding
A. Oraif ....................................................................................................................................................... 11

A Ten-Year Prospective Analysis of Office Hysteroscopic Sterilization
M.D. Levy .................................................................................................................................................... 15

The Effectiveness of Outpatient Thermachoice Endometrial Balloon Ablation: A Long-Term 11-Year Outcome Study
V. Kumar ...................................................................................................................................................... 20

Cultural and Linguistics Competency ......................................................................................................... 23
Plenary 3 – Hysteroscopy

Moderator: Paul D. Indman, Linda D. Bradley
Faculty: Vinod Kumar, Angie Y. Lee, Mark D. Levie, Ayman Oraif, Brenda Sohn, M.P.H. Vleugels

This session provides new concepts in endometrial ablation as well as long-term outcomes of women undergoing the procedure. Also presented are studies of hysteroscopic tubal sterilization, including the effects of counseling in candidate’s decision making process and a large series of office Essure® hysteroscopic tubal sterilization procedures.

Learning Objectives: At the conclusion of this course, the clinician will be able to: 1) List the most important decision-making factors affected by counseling prior to tubal sterilization; 2) evaluate the efficacy and safely of in-office hysteroscopic sterilization; and 3) determine the effect of clinical outcomes of women with abnormal uterine bleeding after endometrial ablation, with and without immediate placement of a levonorgestrel containing intrauterine device.

Course Outline

2:15 Nickel Sensibilization after Essure Sterilization Non Item Anymore? M.P.H. Vleugels
2:25 A Prospective Study on Factors Important to Women Receiving Counseling about Tubal Sterilization and Their Impact on Ultimate Contraception Method Chosen A.Y. Lee
2:35 Resectoscopic Rollerball Endometrial Ablation and Concomitant Levonorgestrel-Releasing Intrauterine System in Women with Abnormal Uterine Bleeding: Is the Combination Better? B. Sohn
2:45 Long-Term Clinical Outcomes of Resectoscopic Endometrial Ablation in Women with Simple and Complex Endometrial Hyperplasia without Atypia and Abnormal Uterine Bleeding A. Oraif
2:55 A Ten-Year Prospective Analysis of Office Hysteroscopic Sterilization M.D. Levie
3:05 The Effectiveness of Outpatient Thermachoice Endometrial Balloon Ablation: A Long-Term 11-Year Outcome Study V. Kumar
3:15 Closing Remarks/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).
Art Arellano, Professional Education Manager, AAGL*
Viviane F. Connor
Consultant: Conceptus Incorporated
Kimberly A. Kho*
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
M. Jonathan Solnik*
Johnny Yi*

SCIENTIFIC PROGRAM COMMITTEE
Ceana H. Nezhat
Consultant: Ethicon Endo-Surgery, Lumenis, Karl Storz
Other: Medical Advisor: Plasma Surgical
Other: Scientific Advisory Board: SurgiQuest
Arnold P. Advincula
Consultant: Blue Endo, CooperSurgical, Covidien, Intuitive Surgical, SurgiQuest
Other: Royalties: CooperSurgical
Linda D. Bradley*
Victor Gomel*
Keith B. Isaacson*
Grace M. Janik
Grants/Research Support: Hologic
Consultant: Karl Storz
C.Y. Liu*
Javier F. Magrina*
Andrew I. Sokol*

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).
Paul D. Indman
Stock Ownership: EndoSee Corp.
Vinod Kumar*
Angie Y. Lee*
Mark D. Levie
Consultant: Bayer Healthcare Corp.
Speakers Bureau: Bayer Healthcare Corp.
Ayman Oraif*
Brenda Sohn*
M.P.H. Vleugels
Other: Trainer: Conceptus Incorporated

Asterisk (*) denotes no financial relationships to disclose.
Objectives:
• Primary objective:
  - Increase of Nickel sensitivity at skin test after Essure device placement.
  - Complaints after Essure device placement related to allergic nickel reaction
• Secondary objectives:
  - Background Nickel sensitivity in our population

Flow chart
- Eligible patients
- Informed consent
- Questionnaire Nickel Patch Test
- Nickel patch Test scored 72 hours later
- Three months later
- Confirmation test
- Questionnaire Nickel patch Test
- Essure procedure

Background: Essure
- Essure procedure — Hysteroscopic sterilisation by placement of microinserts in the proximal tubes
- Micro inserts are stents made of a nickel–titanium alloy = Nitinol, around a body consisting of dacron fibers and stainless steel.
- Nickel leaking test of this device: 0.26µg/day

Background: Nickel sensitivity
- Prevalence of nickel allergic reactions on the skin amongst women in the USA/ north Europe 24%
- Anamnestic complaints of allergic skin reactions are mostly related to wearing of jewelry
- Dietary intake of nickel: 150–900µg/day
Before and after
• Known nickel hypersensitivity,
• Previous positive skin tests in history,
• Dermatologic history
• Allergy, Eczema, Asthma.

After three months extra attention:
• Complaints after Essure procedure
• Symptoms of generalized allergic reactions

Nickel patch test procedure
• Concentrated 1% Nickel Sulfate in petrolatum solution.
• 1 Patch left shoulder containing the solution.
• 1 Control patch right shoulder.
• After 72 hours results were observed and scored.

132 eligible patients.

Questionnaire:

Skin reactions related to jewelery: 32.1%

History of nickel allergic skin reaction: 22.6%

History of positive nickel patch testing: 6.6%

Score 0:
• no reaction

Score 1:
• Erythema

Score 2:
• Erythema
• Papules

Score 3:
• Erythema
• Papules
• Vesicles

Patch tests before placement of microinserts:

• reactions to nickel patch: 26.5%
  - Scores skin reactions:
    1: 13.6%
    2: 11.4%
    3: 1.5%

• reactions to control patch: 1.5%
  - Scores skin reactions:
    1: 0.8%
    2: 0.8%
    3: 0%

Patch tests 3 months after placement of microinserts:

• reactions to nickel patch: 25.7%
  - Scores skin reactions:
    1: 12.1%
    2: 12.1%
    3: 1.5%

• reactions to control patch: 0.8%
  - Scores skin reactions:
    1: 0.8%
    2: 0%
    3: 0%

Only one patient showed a positive skin reaction on the nickel patch after an initial negative reaction;

She had none complaints at all

Provocation of skin sensitisation for nickel patches is known

This lady was part of the first small cohort in which we read the reaction after 48 hours as advised by dermatologists; we experienced more reactions after 48 hours and changed to 72 hours. So maybe she was already positive before.
outcome:

- None of the patients except one developed a positive allergic skin test after a negative skin test pre operatively.
- None of the patients with a positive skin reaction on the nickel patch developed a more severe skin test after Essure sterilisation compared to the initial skin test.
- None of the patients with a positive reaction on the nickel patch after three months mentioned any complaint or systemic symptom.

take home message:

- Essure micro inserts are not related to (de novo) nickel sensitisation.
- Nickel allergy is not a contra-indication for Essure procedure.

Literature:

Clinical expression of nickel contact dermatitis primed by diagnostic patch test.
Theler B, Bucher C, French LE, Ballmer Weber B, Hofbauer GF.

The outcome of an additional patch-test reading on days 6 or 7.
Jonker MJ, Bruynzeel DP.

Adverse events due to suspected nickel hypersensitivity in patients with essure micro-inserts.
Zurawin RK, Zurawin JL.
A Prospective Study on Factors Important to Women Receiving Counseling about Tubal Sterilization and Their Impact on Ultimate Contraception Method Chosen

Angie Y Lee, MD
Director of Ambulatory Services
Bridgeport Hospital, Yale New Haven Health
Assistant Clinical Professor, Yale School of Medicine

Disclosures

- No financial relationships to disclose

Objective

- At the conclusion of this activity, the participant will be able to identify the five factors that should be included in a discussion regarding permanent sterilization

Introduction

- ACOG Practice Bulletin on Benefits and Risks of Sterilization states that the physician performing the procedure has the responsibility of ensuring that the patient is properly counseled concerning the risks and benefits of sterilization.
- “The patient should receive comprehensive and individualized counseling on the reversible alternatives to sterilization and the risks of surgery. The procedure’s intended permanence should be stressed, as well as the possibility of future regret. An estimate of the procedure’s failure rate and risk of ectopic pregnancy should be provided” (ACOG Committee Opinion No 371, July 2007).

Design

- IRB approved prospective cohort study
- 5 Topics discussed
- 5 Teaching aid cards
- Initially asked certainty for tubal sterilization
- At conclusion
  - Certainty for tubal sterilization
  - Contraceptive method
  - Most important topic

Setting

- Urban academic medical center Ob/Gyn clinic
- Yale New Haven Hospital Women’s Center
Patients

- 78 patients - diverse in race, age, marital status

Results: Certainty

- At the beginning, 94.87% of women said they were very sure they wanted tubal sterilization
- After counseling,
  - 55.13% remained very certain
  - 44.87% became less certain

Results: Most Important Topic According to Level of Certainty for Tubal Sterilization

<table>
<thead>
<tr>
<th>Most Important Topic</th>
<th>Alternatives</th>
<th>Risk of Failure/Failure</th>
<th>Permanence</th>
<th>Risk of Regret</th>
<th>Risk of Surgery</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women with Certainty for Tubal Sterilization</td>
<td>6 (13.95%)</td>
<td>4 (9.30%)</td>
<td>17 (39.33%)</td>
<td>4 (9.30%)</td>
<td>12 (27.06%)</td>
<td>42 (100%)</td>
</tr>
<tr>
<td>Women with Decreased Certainty</td>
<td>4 (11.43%)</td>
<td>4 (11.43%)</td>
<td>3 (8.57%)</td>
<td>4 (11.43%)</td>
<td>20 (57.14%)</td>
<td>35 (100%)</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>8</td>
<td>20</td>
<td>8</td>
<td>32</td>
<td>78</td>
</tr>
</tbody>
</table>

p = 0.0154

Results: Decision of Contraceptive Method

<table>
<thead>
<tr>
<th>Decision</th>
<th>Depo-Provera</th>
<th>IUD</th>
<th>Implant</th>
<th>OCP</th>
<th>Tubal Vasectomy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women with Certainty for Tubal Sterilization</td>
<td>0 (0%)</td>
<td>1 (2.3%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>42 (97.67%)</td>
<td>43 (100%)</td>
</tr>
<tr>
<td>Women with Decreased Certainty</td>
<td>1 (2.86%)</td>
<td>22 (62.86%)</td>
<td>9 (25.71%)</td>
<td>1 (2.86%)</td>
<td>0 (0%)</td>
<td>35 (100%)</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>23</td>
<td>9</td>
<td>1</td>
<td>42</td>
<td>78</td>
</tr>
</tbody>
</table>

p < 0.001

Conclusions

- Comprehensive counseling
- Certainty for tubal sterilization decreased from 95% to 55% of women after counseling
- Permanence - most important topic for those remaining sure they want tubal sterilization
- Risks of surgery - most important topic for women who became less sure they wanted tubal sterilization
- LARC

References

- ACOG Practice Bulletin Number 133, Benefits and Risks of Sterilization, February 2013
- ACOG Committee Opinion No 371, Sterilization of Women, Including Those With Mental Disabilities, July 2007
Objective

- To determine clinical outcomes of women with abnormal uterine bleeding (AUB) following treatment with resectoscopic rollerball endometrial ablation alone versus rollerball ablation combined with levonorgestrel intrauterine device (LNG-IUS)

Study Design

- Pilot comparative clinical study (Canadian Task Force Classification II-1) from 2008-2012
- University-affiliated teaching hospital

Patients

- Fifty women (ages 37-43) with AUB of benign pathology and normal intrauterine cavity were treated with either:
  - rollerball endometrial ablation alone (N=25)
  - with a combination of rollerball ablation and LNG-IUS insertion immediately after ablation (N=25)

Interventions

- Endometrial ablation was performed with a 5 mm rollerball monopolar electrode at 120w of power through a 26F (9mm) resectoscope using 1.5% glycine irrigant solution under general anesthesia
Methods

- The LNG-IUS was inserted at the time of the procedure and placement was confirmed hysteroscopically.
- Median follow-up of 2 years (range 1-3)
- Clinical outcomes assessed included rates of amenorrhea/hypomenorrhea, patient satisfaction, need for re-intervention and any complications.

Data Analysis

- Health Sciences Research Ethics Board approval was obtained
- Office and hospital charts were reviewed and the data were recorded anonymously.
- Data were analyzed with Fisher’s Exact and Chi-square test for comparison of nominal data.
- A p value of <.05 was considered to be statistically significant

Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Rollerball + Mirena (N = 25)</th>
<th>Rollerball Controls (N = 25)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>40.7 +/- 6.4 (38.1-43.3)</td>
<td>39.8 +/- 5.6 (37.5-42.1)</td>
<td>.589</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.3 +/- 7.7 (26.0-32.5)</td>
<td>27.8 +/- 6.3 (25.2-27.8)</td>
<td>.453</td>
</tr>
<tr>
<td>Parity</td>
<td>1.8 +/- 1.1 (1.3-3.2)</td>
<td>1.8 +/- 1.0 (1.4-2.2)</td>
<td>.867</td>
</tr>
</tbody>
</table>

Amenorrhea at 2 years

- 91.7% vs. 28.0%
- p < .001

Satisfied or Very Satisfied at 2 years

- 92.0% vs. 68.0%
- p < .034

Re-Intervention

- 12.0% vs. 32.0%
- p < .088
Re-Intervention

<table>
<thead>
<tr>
<th></th>
<th>Rollerball + LNG-IUS (N=25)</th>
<th>Rollerball Controls (N=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat HEA</td>
<td>0</td>
<td>3 (12%)</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>3 (12%)</td>
<td>5 (20%)</td>
</tr>
</tbody>
</table>

Results Summary
- No surgical complications occurred in any group
- The indications for hysterectomy were:
  - Bleeding or pain (adenomyosis)
  - One Mirena required removal due to side effects (h/a, swelling)
- There were no Mirena expulsions requiring re-insertion

Conclusions
- The combination of resectoscopic rollerball endometrial ablation and LNG-IUS significantly improved clinical outcomes in women with AUB as determined by amenorrhea and patient satisfaction rates

References
Introduction

- 1/3 of all gynecological visits are related to abnormal uterine bleeding, 70% are in the peri- and post-menopausal years.
  

- Assessment of the uterine cavity and endometrium by office biopsy, sonography (TVS, SIS) and/or hysteroscopy should be performed in accordance with CPG.

- Office biopsy provides an adequate endometrial specimen in ~ 90% of pre- and post-menopausal women.
  
  Fothergill D et al. BJOG 1992; 9, 779-780.

- The goal of assessing the endometrium is to rule in or out the presence of endometrial hyperplasia (EH) and/or endometrial cancer.

Endometrial hyperplasia was first classified as typical or atypical and further subdivided into simple and complex categories.
  

- The prevalence of simple, complex and atypical hyperplasia was 2.6%, 3%, and 0.7%, respectively, in 531 women with abnormal uterine bleeding between 17 and 54 years of age.

- The risk of progression to endometrial carcinoma of simple and complex hyperplasia without atypia has been estimated to be 1% and 3%, respectively.
  

The continuum concept of EH progressing into atypical EH and endometrial cancer however was challenged by Ferenczy et al.

- These authors, proposed that cytologic atypia is the only important morphologic feature distinguishing endometrial lesions with invasive potential from benign ones.

- They provided elegant arguments that endometrial hyperplasia without atypia is benign, has no potential as a carcinoma precursor and it should be treated conservatively.

- In contrast, endometrial hyperplasia with atypia, which they renamed endometrial intraepithelial neoplasia (EIN), closely resembles well-differentiated, invasive endometrial adenocarcinoma.

- This entity is a significant precursor lesion and is best treated by hysterectomy unless the patient desires to conceive.

- To date, no standard therapy for simple and complex nonatypical hyperplasia has been established.

- Progestins, androgens and metformin have all been used, but the duration of treatment is not well established.

- Although hysteroscopic endometrial ablation has been reported to be an alternative treatment for simple and complex hyperplasia without atypia, no long-term studies thus far have been reported.
  

Objectives

• To determine the feasibility, efficacy, and long-term clinical outcomes of resectoscopic endometrial ablation (REA) as primary treatment of simple and complex endometrial hyperplasia without atypia in women with abnormal uterine bleeding.

Materials and Methods

• From January 1990 through December 2012, GAV performed 4,729 primary REA for AUB.

• Among these there were 161 women with non-atypical hyperplasia.

• At REA, 6 were found to have atypical hyperplasia (4 CH, 2 SH) and were treated accordingly.

• 1 additional had incidental adenosarcoma treated by HBSO+adjunct.

• 154 women without atypia were treated by REA
  – 102 with SH
  – 52 with CH

Materials and Methods

• Surgery was performed by Fellows/Senior Residents supervised by GAV.

• Endometrium was ablated by resection with 8 mm loop electrode, 3-5 mm rollerballs or a combination of both.

• A 9 mm (26F) resectoscope with 1.5% glycine and 120 W of power were used.

• As a rule, resection rather than rollerball was performed in the absence of a recent (6 months) negative endometrial biopsy; in the presence of intrauterine polyp(s), myoma(s), or suspicious lesion(s); and in women with any risk factors for endometrial neoplasia.

• Endometrial biopsy was attempted in all patients pre-operatively and it was compared with postoperative histopathology.

• Patients were evaluated annually through clinic visits.

Results

Simple non-atypical hyperplasia

• 102 women.

• Endometrium was ablated by:
  – Resection-78(76.4%)
  – Rollerball-22 (21.5%)
  – Combination of both-2 (1.9%)

• Patient Comorbidities included:
  • Hypertension-6
  • Diabetes-7
  • Breast cancer-3
  • Hypothyroidism-8

Figure

Age distribution of 103 women with abnormal uterine bleeding diagnosed with simple endometrial hyperplasia

Figure

Body Mass Index (BMI) of 103 women with abnormal uterine bleeding diagnosed with simple hyperplasia
Office and post-hysteroscopic endometrial biopsy results in 107 women with abnormal uterine bleeding diagnosed with simple endometrial hyperplasia

<table>
<thead>
<tr>
<th>Office endometrial biopsy</th>
<th>Number</th>
<th>Intra-Ablation Histopathology</th>
<th>Number</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal endometrium</td>
<td>48</td>
<td>Normal Endometrium</td>
<td>48</td>
<td>Resection 24, Rollerball 10, Combined 4</td>
</tr>
<tr>
<td>Simple hyperplasia</td>
<td>47</td>
<td>Simple hyperplasia</td>
<td>46</td>
<td>Resection 27, Rollerball 10, Combined 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Complex hyperplasia with Atypia</td>
<td>5</td>
<td>Resection 3, Rollerball 1, Combined 2</td>
</tr>
<tr>
<td>Inadequate sample</td>
<td>10</td>
<td>Simple hyperplasia</td>
<td>10</td>
<td>Resection 10</td>
</tr>
<tr>
<td>Unable to do</td>
<td>12</td>
<td>Simple hyperplasia</td>
<td>12</td>
<td>Resection 12</td>
</tr>
</tbody>
</table>

Outcomes of 102 Women with Simple non-atypical hyperplasia

- There were no perioperative complications.
- 3 patients were lost to follow up.
- 1 died 5 years after surgery due to natural causes.
- 6 patients had subsequent hysterectomy:
  - 2 Chronic pelvic pain
  - 2 persistent bleeding
  - 1 benign ovarian cyst
  - 1 fibroids with pressure symptoms
- 92 women had a median follow-up of 6.5 years (0.5-14)

Clinical Outcomes of 92 women with Simple Hyperplasia

- Amenorrhea: 87 (94.6%)
- Spotting: 5 (5.4%)
  - TV U/S in all showed endometrial lining < 5 mm
- Satisfaction: 92 (100%)

Histopathology of the 6 Hysterectomy Specimens

- 5 had no residual endometrial hyperplasia
- 1 pathology not available.

Results

Complex non-atypical Endometrial Hyperplasia

- 52 patients
- Endometrium was ablated by:
  - Resection 38 (73%)
  - Rollerball 11 (21.1%)
  - Combination of both 3 (5.7%)
- Patient Comorbidities included:
  - Hypertension-19
  - Diabetes-7
  - Cerebrovascular disease-3
  - Cardiovascular disease-4

Pre- and post-hysteroscopic endometrial biopsy results in 54 women with abnormal uterine bleeding diagnosed with complex hyperplasia

<table>
<thead>
<tr>
<th>Office endometrial biopsy</th>
<th>Number (N=54)</th>
<th>Intra-hysteroscopic Histopathology</th>
<th>Number (n=54)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal endometrium</td>
<td>20</td>
<td>CH</td>
<td>20</td>
<td>Resection 6, Rollerball 11, Combined 4</td>
</tr>
<tr>
<td>Normal endometrium</td>
<td>9</td>
<td>CH</td>
<td>9</td>
<td>Resection 6</td>
</tr>
<tr>
<td>Normal endometrium</td>
<td>4</td>
<td>CH</td>
<td>4</td>
<td>Resection 6</td>
</tr>
<tr>
<td>Simple hyperplasia</td>
<td>13</td>
<td>CH</td>
<td>13</td>
<td>Resection 6, Rollerball 11, Combined 4</td>
</tr>
<tr>
<td>Simple hyperplasia</td>
<td>7</td>
<td>CH</td>
<td>7</td>
<td>Resection 6</td>
</tr>
<tr>
<td>Simple hyperplasia</td>
<td>7</td>
<td>CH</td>
<td>7</td>
<td>Resection 6</td>
</tr>
<tr>
<td>Simple hyperplasia</td>
<td>1</td>
<td>CH</td>
<td>1</td>
<td>Resection 6</td>
</tr>
<tr>
<td>Inadequate sample</td>
<td>3</td>
<td>CH</td>
<td>3</td>
<td>Resection 6</td>
</tr>
<tr>
<td>Unable to do</td>
<td>6</td>
<td>CH</td>
<td>6</td>
<td>Resection 6</td>
</tr>
</tbody>
</table>
Clinical Outcomes of 52 women with Complex Hyperplasia

- There were no perioperative complications.
- All 52 (100%) patients had follow up.
- 6 patients had subsequent hysterectomy:
  - 4 for persistent bleeding
  - 1 for benign ovarian mass
  - 1 for pelvic organ prolapse
- Median follow up of 6 years (0.5-17).

Clinical Outcomes of 52 women with Complex Hyperplasia

- Amenorrhea: 45 (98%)
- Spotting: 1 (2%)
  - TV U/S: endometrial lining 4 mm
- 46 (100%) were satisfied

Histopathology of 6 Hysterectomy Specimens

- There was no residual endometrial hyperplasia in all specimens.

Conclusion

- Resectoscopic endometrial ablation is a feasible, safe and effective treatment of simple and complex endometrial hyperplasia without atypia in women with abnormal uterine bleeding by experienced surgeons.

### Case Details

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Initials</th>
<th>Date of Birth</th>
<th>Age (Yr)</th>
<th>Parity</th>
<th>BMI</th>
<th>Comorbidities</th>
<th>Office Biopsy</th>
<th>REA Date</th>
<th>ABL Procedure</th>
<th>Post-REA Histopathology</th>
<th>Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>C</td>
<td>Feb. 1992</td>
<td>46</td>
<td>G1P1</td>
<td>32</td>
<td>Hypertension, Endometriosis</td>
<td>Rollerball CH</td>
<td>1992</td>
<td>Hysterectomy, Hymetrical adenocarcinoma (G1/3), focal invasion of cervical stroma &amp; outer half of myometrium, adenomyosis</td>
<td>22 years: Colorectal resection, Colon adenocarcinoma, nodes positive (68yr)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>A</td>
<td>Apr. 2004</td>
<td>70</td>
<td>G4P4</td>
<td>35</td>
<td>Hypertension, Ischemic heart disease</td>
<td>1989 SH</td>
<td>1992 SH</td>
<td>Resection, CH with atypical glandular metaplasia</td>
<td>5 years: Died of Colon cancer</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>S</td>
<td>June 1998</td>
<td>57</td>
<td>G3P3</td>
<td>29</td>
<td>None</td>
<td>Resection</td>
<td>1998 SH</td>
<td>Resection</td>
<td>CH with atypia</td>
<td>15 years: Amenorrhea (73yr, A&amp;W)</td>
</tr>
<tr>
<td>5</td>
<td>S</td>
<td>Dec. 2001</td>
<td>64</td>
<td>G1P1</td>
<td>26</td>
<td>Diabetes, Hypertension, Emphysema</td>
<td>1999 SH</td>
<td>2000 SH</td>
<td>Resection, CH with atypia</td>
<td>5 years: Died of Lung cancer</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>Dec. 2004</td>
<td>52</td>
<td>G1P1</td>
<td>27</td>
<td>Sarcoidosis</td>
<td>Resection</td>
<td>2004 SH</td>
<td>Resection, CH with atypia</td>
<td>3 months: THBSO, Pathology: CH without atypia</td>
<td></td>
</tr>
</tbody>
</table>
A Ten Year Prospective Analysis of Office Hysteroscopic Sterilization

Mark Levie, MD, Scott Chudnoff, MD, Holly Yettaw Luts, MD
Department of Obstetrics/Gynecology and Women's Health
Albert Einstein College of Medicine
Montefiore Medical Center

Disclosures
- Consultant: Bayer Healthcare Corp.
- Speakers Bureau: Bayer Healthcare Corp.

Objectives
- To prospectively evaluate the efficacy and safety of in-office hysteroscopic sterilization
- To analyze follow up hysterosalpingogram data
- To assess factors that may predict procedural success
- To assess for unintended pregnancies post Essure

Methods
- This was a prospective cohort of patients undergoing Essure office hysteroscopic sterilization from June 2002 - February 2012 at an urban academic faculty practice
- All patients presenting for Essure were offered participation
- All procedures were performed in an office based setting
- Patients were premedicated with only NSAID's and paracervical block without sedation
- Demographic, medical and surgical history as well as procedural data (procedural time, successful placement, reasons for unsuccessful placements) were collected
- 3 month post-procedure HSG data was recorded

Demographics

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>35.4 (22, 47; SD 5.1)</td>
</tr>
<tr>
<td>BMI</td>
<td>30.1 (17, 59.3; SD 6.6)</td>
</tr>
<tr>
<td>Procedure Time (min)</td>
<td>6.5 (2, 35; SD 5.3)</td>
</tr>
<tr>
<td>Parity</td>
<td>2.7 (0, 10; SD 1.2)</td>
</tr>
<tr>
<td>Vaginal Deliveries</td>
<td>2.2 (0, 9; SD 1.4)</td>
</tr>
<tr>
<td>Cesarean Sections</td>
<td>0.5 (0, 4; SD 0.8)</td>
</tr>
<tr>
<td>TOP</td>
<td>1.2 (0, 12; SD 1.6)</td>
</tr>
<tr>
<td>h/o PID</td>
<td>13</td>
</tr>
<tr>
<td>h/o Gonorrhea</td>
<td>18</td>
</tr>
<tr>
<td>h/o Chlamydia</td>
<td>76</td>
</tr>
<tr>
<td>Prior Abdominal Surgery</td>
<td>390</td>
</tr>
</tbody>
</table>

Demographics

<table>
<thead>
<tr>
<th>Level of Education</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; HS</td>
<td>1%</td>
</tr>
<tr>
<td>HS</td>
<td>46%</td>
</tr>
<tr>
<td>&gt; HS</td>
<td>37%</td>
</tr>
<tr>
<td>Declined to state</td>
<td>16%</td>
</tr>
</tbody>
</table>
751 women consented and had the procedure performed.
- 695 (92.7%) had initial successful bilateral placement
- 11 (1.5%) had intentional unilateral placement
- 706 (94%) had initial successful placement

34 (4.4%) had unsuccessful placement (no device)
- 11 (1.5%) had unintentional unilateral placement
- 7 had secondary procedures with bilateral successful placement
- Ultimately 713/751 (95%) had successful placement

Follow-up HSG's were performed in 535/713 (75%) patients with placement.
Intent to Treat (N=751)

Successful Bilateral (N=695)

HSG Performed (N=521)

Bilateral Occlusion 3 months (N=492)

Bilateral Occlusion 6 months (N=14)

Second Procedure Occluded (N=1)

Not Occluded (N=13)

Intentional Unilateral (N=11)

HSG Performed (N=8)

Bilateral Occlusion 3 months (N=6)

Bilateral Occlusion 6 months (N=1)

Second Procedure Occluded (N=1)

Unintentional Unilateral (N=11)

Successful Second Procedure (N=4)

HSG Performed (N=3)

Bilateral Occlusion (N=3)

Unsuccessful (N=34)

Successful Second Procedure (N=3)

HSG Performed (N=3)

Bilateral Occlusion (N=3)

Follow-up HSG’s were performed in 535/713 (75%) patients with placement.

12 (2.3%) demonstrated unilateral occlusion

504/535 (94.2%) had bilateral occlusion on initial HSG

522/535 (97.6%) had bilateral occlusion at 6 months on HSG

Decreasing procedure time with increasing experience

Average procedure time decreased from 12 minutes to 5 minutes. This was a statistically significant decrease (p <0.001)

The average time for successful placement was 8 minutes with 75% of the successful placements in 10 minutes or less.

BMI – Two Sample T Test

There is no statistically significant difference in the BMI between the successful and unsuccessful placements.

Prior Pelvic Infection – Chi2

Successful placement in patients without prior pelvic infections was 94% and with prior pelvic infections was 92%.

There is no statistically significant difference.

BMI

Unsuccessful Placement

Successful Placement

Failure

Success

0

200

400

600

800

2_8a_ProcedureTime

Fitted values

95% CI

Unsuccessful Placement

Successful Placement

0

10

20

30

40

3_8a_ProcedureTime

Unsuccessful Placement

Successful Placement

p 0.0913

p 0.0913

p 0.0913

p 0.316

p 0.316

p 0.316

p 0.316
Prior Abdominal Surgery – Chi$^2$

<table>
<thead>
<tr>
<th></th>
<th>Unsuccessful Placement</th>
<th>Successful Placement</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Prior</td>
<td>21</td>
<td>340</td>
<td>361</td>
</tr>
<tr>
<td>Prior Abdominal Surgery</td>
<td>24</td>
<td>366</td>
<td>390</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>706</td>
<td>751</td>
</tr>
</tbody>
</table>

Successful placement in patients without prior abdominal surgery was 94% and with prior abdominal surgery was 94%. There is no statistically significant difference. Pearson chi$^2(1) = 0.0377$ p 0.846

Prior Vaginal Delivery – Chi$^2$

<table>
<thead>
<tr>
<th></th>
<th>Unsuccessful Placement</th>
<th>Successful Placement</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Prior</td>
<td>10</td>
<td>92</td>
<td>201</td>
</tr>
<tr>
<td>Prior Vaginal Delivery</td>
<td>35</td>
<td>613</td>
<td>648</td>
</tr>
<tr>
<td>Total</td>
<td>45</td>
<td>705</td>
<td>750</td>
</tr>
</tbody>
</table>

Successful placement in patients without prior vaginal delivery was 90% and with prior vaginal delivery was 95%. There is no statistically significant difference. Pearson chi$^2(1) = 3.0288$ p 0.082

Results

- In univariate and multivariate analysis, no demographic factors (e.g., age, BMI, parity, vaginal deliveries, STD history, prior abdominal surgery) or procedural factors (e.g., number of trailing coils, use of paracervical block, amount of fluids) were associated with successful placement.
- There were no major complications associated with the procedure.

Pregnancy Rates

- 7 documented unintended pregnancies following Essure procedure:
  - 1 IUP in the first month post procedure
  - 2 IUP with intentional unilateral placement for h/o ectopic with salpingectomy
- 1% of the patients with successful Essure placement had documented pregnancies
- 0.7% of the patients with reported occlusion on HSG had documented pregnancies
- 18
- 1 <3 months post Essure
- 2 >3 months post Essure without confirmatory HSG
- 4 HSG reported occlusion
- 2 unilateral placement for prior unilateral salpingectomy
- 1 Essure perforating uterine wall
- 1 with >50% of the device in the cavity
Unilateral Occlusion with Prior Salpingectomy

Misplaced Essure perforating the Uterine wall

Greater than 50% of Device in the Cavity

Unintended pregnancy post Essure

- Risk of unintended pregnancy following Essure is 1%
- All pregnancies that were identified were intrauterine pregnancies

Conclusion

- Office hysteroscopic sterilization can be performed safely and effectively in an office-based setting with minimal analgesia. There are no patient specific characteristics identified that would predict successful placement or occlusion.
The Effectiveness of Outpatient Thermachoice Endometrial Balloon Ablation: A Long-Term 11-Year Outcome Study

Dr Vinod Kumar
PhD, BMBS
University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

DISCLOSURE
No financial relationships to disclose

Learning Objectives
• At the conclusion of this activity, participants will be better able to
  – explain the long-term treatment outcomes of outpatient Thermachoice balloon endometrial ablation under a direct local anaesthetic cervical block (LA-Thermachoice)

Background
• Endometrial ablation techniques are well-established alternatives to hysterectomy for the management of women with heavy menstrual bleeding (HMB) 13, 15
• Thermachoice endometrial ablation technique (Gynecare; ethicon Inc., Somerville, NJ, USA) involves using a heated fluid-filled balloon to thermally ablate the endometrial tissue
• This system has undergone significant improvement from the first generation Thermachoice (TBEA) to a third generation Thermachoice III (TBEA-III) in 2003 5, 6

Aims
• 1°: To evaluate the long-term treatment outcomes of LA-Thermachoice i.e. up to 11-year period after the procedure
• 2°: To determine if any further interventions such as repeat LA-Thermachoice, treatment with the LNG-IUS or hysterectomy were required to control symptoms since LA-Thermachoice

Background
• We previously compared the clinical outcome and effectiveness of TBEA and TBEA-III devices and reported 3-years post-treatment follow-up results 18:
  – Treatment satisfaction was high in both cohorts (combined satisfaction rate 76 %)
  – TBEA-III was associated with a higher amenorrhoea rate (35 %) compared to the TBEA device (23 %)
Methods

- **Design:** Prospective cohort study and a postal questionnaire survey
- **Setting:** A UK teaching hospital
- **Patients:** 253 women with HMB undergoing LA-Thermachoice over an 11-year period between 2001 and 2011
  - A computer database was maintained and populated with the relevant peri-operative information from all patients undergoing LA-Thermachoice

A postal questionnaire, including two further postal reminders 3 months apart to non-responders, were sent between February 2012 and August 2012 to evaluate post-treatment symptoms and to determine the long-term effectiveness of therapy

Main outcome measures: Treatment success measured by postoperative bleeding patterns, improvement in dysmenorrhoea, patient satisfaction and post-procedure hysterectomy rates

---

### Flowchart of the study population of patients treated with LA-Thermachoice between 2001 and 2011

- **LA-Thermachoice patient identification data** entered into a computerised database, n = 253
- Excluded from survey, n = 10
  - not all identification data recorded, n = 5
  - procedure abandoned due to pain or technical problems, n = 4
  - patient deceased due to natural cause, n = 1
- Questionnaire sent, n = 243
  - Non-responders despite two postal reminders, n = 52
- Completed questionnaire received and analysed, n = 190

---

### Table: Demographics and intraoperative data of women undergoing LA-Thermachoice between 2001 and 2011, n = 253

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>44</td>
<td>4.7</td>
</tr>
<tr>
<td><strong>BMI, n = 240</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>30</td>
<td>6.8</td>
</tr>
<tr>
<td><strong>Cycle phase, n = 247</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proliferative</td>
<td>93</td>
<td>37%</td>
</tr>
<tr>
<td>Secretory</td>
<td>91</td>
<td>37%</td>
</tr>
<tr>
<td>Menstruating</td>
<td>34</td>
<td>14%</td>
</tr>
<tr>
<td>Mid cycle</td>
<td>15</td>
<td>6%</td>
</tr>
<tr>
<td>Amenorrhoe due to drugs</td>
<td>14</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Clinical findings (USS or hysteroscopic), n = 249</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>191</td>
<td>77%</td>
</tr>
<tr>
<td>Intramural fibroid</td>
<td>39</td>
<td>15%</td>
</tr>
<tr>
<td>Submucosal fibroid &lt; 3 cm</td>
<td>5</td>
<td>2%</td>
</tr>
<tr>
<td>Polyp</td>
<td>7</td>
<td>3%</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Uterine size, cm, n = 249</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10</td>
<td>184</td>
<td>74%</td>
</tr>
<tr>
<td>≥10</td>
<td>43</td>
<td>17%</td>
</tr>
<tr>
<td>Not recorded</td>
<td>22</td>
<td>9%</td>
</tr>
<tr>
<td>Mean size (SD)</td>
<td>8.6</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>Volume of fluid, ml</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermachoice, n = 51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>24.1</td>
<td>13.3</td>
</tr>
<tr>
<td>Thermachoice-III, n = 185</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>19.1</td>
<td>11.2</td>
</tr>
<tr>
<td><strong>Intrauterine pressure, mm Hg</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermachoice, n = 51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>157</td>
<td>16</td>
</tr>
<tr>
<td>Thermachoice-III, n = 188</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>179</td>
<td>16</td>
</tr>
<tr>
<td><strong>Mean visual analogue (VAS) immediately after procedure, n = 234</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>5.5</td>
<td>2.7</td>
</tr>
<tr>
<td>Not severe (VAS ≤ 8)</td>
<td>200</td>
<td>81%</td>
</tr>
<tr>
<td>Severe (VAS ≥ 9)</td>
<td>34</td>
<td>14%</td>
</tr>
</tbody>
</table>

aData not reported in all cases, calculations based on cases that were recorded

---

### Discussion: strengths of this study

- Long-term follow-up
  - up to 134 months (median 71 months)
- A good response rate to our survey
  - 78% of women completed the survey
- The reported satisfaction rates with LA-Thermachoice in our study are in agreement with previously reported satisfaction rates (range 80–95%)
Discussion: limitations of this study

- The study population may be heterogeneous in relation to different HMB bleeding patterns
- Baseline quality-of-life data were not collected
- 5% of women who have subsequently undergone menopause would positively bias the results, but these patients were discounted from the results

Conclusions

- Patient satisfaction with LA-Thermachoice is high, and is maintained over a long period of time after the procedure
- LA-Thermachoice is an effective treatment option for women with symptoms of HMB and a robust alternative to hysterectomy

References

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.