Endometrial Ablation:
Causes and Management of Its Failures

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Professional Education Information

**Target Audience**
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Endometrial ablation, beginning with the electrosurgical technology of the Resectoscope and Rollerball, and expanding with newer generation intrauterine destruction technologies using heat, radiofrequency and freezing, has become an important procedure in the management of abnormal uterine bleeding. Newer development of medications and intrauterine devices delivering hormones to the endometrium have further defined the roles of all of uterine conservation techniques used for this enormous clinical problem. This tutorial will discuss the selection of patients for endometrial ablation to reduce failures and to understand the causes and management of such failures.

Learning Objectives: At the conclusion of this course, the participant will be able to: 1) Use the learning process to understand the role endometrial ablation plays in the management of abnormal uterine bleeding; 2) discuss how to select the proper candidates for the procedure; and 3) explain what to do and how to do it when the procedure has failed.
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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Consultant: Conceptus Incorporated
Kimberly A. Kho*
Frank D. Loffer, Executive Vice President/Medical Director, AAGL*
Linda Michels, Executive Director, AAGL*
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Other: Royalty: Olympus
Motti Goldenberg*

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Endometrial Ablation: Causes and Management of Its Failures

Moderator: Stephen L. Corson

Panelists: Philip G. Brooks MD
          Moty Goldenberg MD

Other: Royalty: Olympus

Objective

- To identify preexisting conditions that may increase the failure rate for endometrial ablation and to document and discuss strategies and solutions to deal with this problem

Shavell

- 1162 evaluable patients
- 157 (13.4%) with hysterectomy
- Mean/median follow-up 39 months
- Time to hysterectomy 1-64 months, 80% by 3 years
- Adenomyosis in 44% of specimens

Fig. 1

Fig. 2
Fürist, Philipsen, Joergensen

Ablations 1993-5
61 coag, 59 resection
10 year follow-up
63% one, 11% two ablations
22% hysterectomy (17% < 40)
No difference by technique

Glasser, Heinlein, Hung
JMIG 2009; 16:700-7

• 231 Analyzed over 5.5 years for results of submucous myomas vs. no myomas
• Failure rate with submucous myoma =23%
• Failure rate with no myoma 3.7%
• Actual hysterectomy rate was 11.6% vs. 0.7%
• HTA system as in-office procedure with local anesthesia
Prognosis for Failure

- Patient Age
- Prior cesarean Section
- Submucous myoma
- Distorted cavity
- Large cavity
- Bleeding disorder
- Multiple mural myomas
- Previous failed ablation
- Adenomyosis
Endometrial Ablation: Causes and Management of Its Failures

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DISCLOSURES
I have no financial relationships to disclose.

WHAT TO DO WITH THE FAILURES

- Standard Surgical Treatment:
  - D & C, Hysterectomy
- Medical Therapy:
  - Mirena, Lysetda, Hormonal Therapy,
- Repeat Ablation:
  - Same Method
  - Different Method

WHY NOT JUST REPEAT THE ABLATION?

Table 1. Univariate Analysis of Potential Risk Factors for Postablation After Endometrial Ablation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Hysterectomy</th>
<th>Postablation</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>2,857 (73%)</td>
<td>274 (31)%</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>48.8 (25.5)</td>
<td>49.0 (25.9)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Younger than 40</td>
<td>224 (74.6)</td>
<td>237 (93.9)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>40-49.9</td>
<td>576 (73.4)</td>
<td>206 (39.5)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>50-59.9</td>
<td>599 (60.1)</td>
<td>778 (64.2)</td>
<td></td>
</tr>
<tr>
<td>60-69.9</td>
<td>334 (56.5)</td>
<td>51 (81.7)</td>
<td></td>
</tr>
<tr>
<td>70+ years</td>
<td>100 (50.0)</td>
<td>15 (88.2)</td>
<td></td>
</tr>
<tr>
<td>Endometrial ablation technique</td>
<td></td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Linearized</td>
<td>307 (72.5)</td>
<td>147 (22.2)</td>
<td></td>
</tr>
<tr>
<td>Microwave</td>
<td>295 (74.6)</td>
<td>217 (38.9)</td>
<td></td>
</tr>
<tr>
<td>Radiotherapy</td>
<td>339 (70.9)</td>
<td>68 (62.0)</td>
<td></td>
</tr>
<tr>
<td>Thermal therapy</td>
<td>38 (36.1)</td>
<td>8 (12.3)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>607 (73.0)</td>
<td>42 (91.7)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Laminaria</td>
<td>275 (77.2)</td>
<td>93 (22.8)</td>
<td></td>
</tr>
<tr>
<td>No laminaria</td>
<td>207 (53.4)</td>
<td>165 (31.9)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Surgical setting</td>
<td>2,398 (75%)</td>
<td>303 (31%)</td>
<td></td>
</tr>
<tr>
<td>Laparoscopy</td>
<td>241 (73%)</td>
<td>99 (31%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are n (%) unless otherwise specified.
REPORTED FAILURE RATES BY DEVICE

• THERMACHOICE™*
  May vary according to balloon I, II, & III
  Varies according to length of time since procedure
  16.5% @ 3 yrs; additional 17% yrs. 3-5
  at 5 yrs, report 42 hysterectomies, 5 repeat ablations,
  1 D&C
  Repeat ablations reported as both Thermachoice and
  Rollerball


• NOVASURE™*(Bipolar Array)
  Reports 10% failure at 1 yr.
  2.8 Hysterectomy rate at 3 yrs
  Repeat treatment in 12/146 pts. (8.2%)
  2 repeat Novasures.


• MEA™ (MICROSULIS ENDOOMETRIAL ABLATION)
  12 month failure rate = 4%
  3 year Hysterectomy rate = 4%
  No discussion or retreatment rate or method


• HER OPTION™*(CRYOABLATION THERAPY)
  Hysterectomy @ 30 months = 7%
  Retreatment rate @ 30 months = 13%
  2.7% repeat CryoAblation

HER OPTION™ THREE YEAR RESULTS
ROY, DULEBA & TOMINSEN, JMIG 2/07

- Telephone interview (not PBAC chart) of 152 of 279 original pts. (108/193 CRYO vs 44/86 REA)
- Reduction of bleeding levels to "normal levels or below" in 92.2% of CRYO and 92.1% of REA
- Amenorrhea rates: 26% CRYO & 34% REA
- Hysterectomy or re-treatment: 11% CRYO & 15% REA
- Repeat treatment occurred in 34 pts. (CRYO 19, REA 8, HYSTERECTOMY 7) with 14 additional pts. (CRYO 11, REA 3) sought treatment for AUB without repeat ablation or hysterectomy

REPORTED FAILURE RATES BY DEVICE

- HTA™* (HYDROTHERMABLATOR)
  - Hysterectomy rate @ 3 yrs = 9%
  - Repeat HTA 2%

RESECTOSCOPIC RE-ABLATION UNDER ULTRASOUND GUIDANCE*

- Retreated 50 pts. who had late complications after GEA: Mainly AUB & cyclic pelvic pain;
- 33 Novasure™, 10 HTA™, 6 Thermachoice™, 1 HerOption™
- Used 22 or 26 fr. resectoscope under transabdominal u.s. guidance; glycine (unipolar) or saline (bipolar) distension; pressures of 120 – 180 mm Hg; all under conscious sedation (midazolam, fentanyl)


RESULTS (avg. follow-up 18 months):
- 40 pts. (80%) had no pain, no heavy periods
- 2 pts. amenorrhea and mild cyclic pain
- 2 pts. amenorrhea and mod. cyclic pain
- 5 pts. amenorr. or oligomenorr. & severe cyclic pain:
  - 3 had lapsed hysteroscopies, 2 had repeat UGRH
- 3 hysterectomies so far, 2/3 with adenomyosis, 1 myomas

CONCLUSION

- Endometrial Ablation is very successful in controlling AUB
- Failure rates range from 10 to 30% and may vary according to age at the time of the procedure, time since the original procedure and other pathology encountered (myomata, etc)
- Hysterectomy for failures reported in 15 to 25% of ablations
- Reports of repeat ablation for failures are few but seemingly effective in reducing hysterectomy rates
- A new study of re-operative hysteroscopy under Ultrasound guidance looks very promising
REFERENCES

Endometrial Ablation: Causes and management of its Failures

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Head.
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ISRAEL

OBJECTIVES

Trainee would be able to
• Recognize the reasons for hysteroscopic endometrial ablation failure
• Implement better pre operative care
• Prepare for and manage failure in a more constructive method

What is the failure Rate?

At 12 Months (PBAC>75)

<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Failure/No.</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooper 1999</td>
<td>25/116</td>
<td>21%</td>
</tr>
<tr>
<td>Cooper 2002</td>
<td>18/154</td>
<td>11%</td>
</tr>
<tr>
<td>Cooper 2004</td>
<td>28/215</td>
<td>13%</td>
</tr>
<tr>
<td>Corson 2001</td>
<td>19/167</td>
<td>23%</td>
</tr>
<tr>
<td>Soysal 2001</td>
<td>11/45</td>
<td>24%</td>
</tr>
<tr>
<td>ACOG 2007</td>
<td></td>
<td>24%</td>
</tr>
</tbody>
</table>

Predictors of Failure

Gemer et. Al:
- 128 women
- 10% failure
- Adenomyosis was not present in the histology

Loninotti et. Al:
- 3,681 women 26% Hysterectomy
- Both 1st and 2nd generation AGE is the major factor
- Type of endometrial ablation procedure, setting of endometrial ablation procedure & presence of leiomyomas were not predictors of hysterectomy.
• 157 of 1169 women (13.4%) who had hysterectomy following ablation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hysterectomy before ablation</th>
<th>Hysterectomy after ablation</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.6 ± 10.0</td>
<td>58.6 ± 10.0</td>
<td>0.32</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>70.4 ± 12.6</td>
<td>70.4 ± 12.6</td>
<td>0.9</td>
</tr>
<tr>
<td>Body mass index (BMI)</td>
<td>27.3 ± 4.9</td>
<td>27.3 ± 4.9</td>
<td>0.86</td>
</tr>
<tr>
<td>Preoperative menorrhagia</td>
<td>Yes</td>
<td>Yes</td>
<td>0.2</td>
</tr>
<tr>
<td>Presence of adenomyosis</td>
<td>Yes</td>
<td>Yes</td>
<td>0.45</td>
</tr>
</tbody>
</table>

- Adenomyosis was present in 44.4% of hysterectomy specimens

• Adenomyosis was present in 44.4% of hysterectomy specimens.

- BASAK and Shaha 2009:
  - 1017 hysterectomies. In 26 pathological report:
    - Adenomyosis
  - Evaluation of the clinical data of those 26 patients
  - 20 suffered from menorrhagia, 9 dysmenorrhea

GnRH Before operation

When compared with no treatment, GnRH analogues are associated with a shorter duration of surgery, greater ease of surgery and a higher rate of post-operative amenorrhea at 12 months with hysteroscopic resection or ablation. Post-operative dysmenorrhoea also appears to be reduced.

• 62 Vs. 59 pt. No Diff. In results after 5 Y
ACOG Bulletin 81:
At this time, there are no high-quality data that allow for objective evaluation of similar outcomes associated with other preoperative approaches such as systemic progestins or mechanical preparation of the endometrium with curettage.

Mirena & Ablation
- Vaughan et. Al.
- Observational, f/o questionnaire
- 105 patients follow-up 25 months (6 – 54)
- 50.5% described lighter periods
- 46% had become amenorrhoeic
- 96% satisfied
- Higher success rate?

What is this phenomenon?
- Uncommon form of abnormal uterine bleeding
- The cross-section incision of the inferior segment can cause a bulging, which creates a pouch in the isthmus
- This facilitates the accumulation of menstrual blood in this site and postmenstrual spotting

The Nitch/Pouch/Defect

Dilated vessels
Internal OS
Borges 2010
• The prevalence of a niche on evaluation with TVS and GIS was 24.0% and 56.0%, respectively.
• A niche was considered to be present if the depth was at least 1 mm visualized with GIS.

• Postmenstrual spotting was reported by 33.6% of women with a niche and 15.2% of Women without a niche (P = 0.002).

Surgical treatment and follow-up of women with intermenstrual bleeding due to Cesarean section scar defect

• 9/11 (82%) of these patients with the desire to become pregnant were unable to conceive succeeded between 14- and 24-months of follow-up.

• 20/24 (84%) of patients remained asymptomatic (without bleeding disturbances) after surgery.

Cecilia Fabres JMG 2005

The surgical technique

Hysteroscopic Focal Ablation

9/11 (82%) of these patients with the desire to become pregnant were unable to conceive succeeded between 14- and 24-months of follow-up.

20/24 (84%) of patients remained asymptomatic (without bleeding disturbances) after surgery.

Fabres, 2005
Can all Nitches be treated histeroscopically?

- In some cases the pouch extends into the parmetria

Duration of PAUB

Huge Scar Saculation

Diagnostic Hysteroscopy

Laparoscopic View
Conclusion

- Avoid operating:
  - Patients with adenomyosis
  - Young patients
  - Patients with fibroids
- Resection or Ball – does not matter for failure rate
- GnRH is not needed
- Mirena – an intriguing option to add
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.