Endometrial Ablation

Description

Endometrial ablation is a potential alternative to hysterectomy for menorrhagia. A variety of approaches are available; these are generally classified into hysteroscopic techniques (e.g., Nd:YAG laser and electrosurgical rollerball) and non-hysteroscopic techniques (e.g., cryosurgical and radiofrequency (RF) ablation).

Background

Ablation or destruction of the endometrium is used to treat menorrhagia in women who failed standard therapy. It is considered a less invasive alternative to hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who wish to preserve their fertility.

Multiple energy sources have been used. These include: the neodymium-yttrium aluminum garnet (Nd-YAG) laser; a resecting loop using electric current; electric rollerball; and thermal ablation devices. Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium.

Techniques for endometrial ablation are generally divided into two categories: those that do and do not require hysteroscopic procedures. (Other terminology for these categories of techniques include first-generation versus second-generation procedures and resectoscopic versus non-resectoscopic endometrial ablation methods). Hysteroscopic techniques were developed first; the initial technique was photovaporization of the endometrium using an Nd-YAG laser, and this was followed by electrosurgical ablation using an electrical rollerball or electrical wire loop. (The latter technique is also known as transcervical resection of the endometrium or TCRE). Hydrothermal ablation also involves hysteroscopy. Hysteroscopic techniques require skilled surgeons and, due to the requirement for cervical dilation, use of general or regional anesthesia. In addition, the need for the instillation of hypotonic distension media creates a risk of pulmonary edema and hyponatremia such that very accurate monitoring of fluids is required.
Nonhysteroscopic techniques can be performed without general anesthesia and do not involve use of a fluid distention medium. Techniques include thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency (RF) ablation.

There are concerns about maternal and fetal morbidity and mortality associated with pregnancy after endometrial ablation. Thus, U.S. Food and Drug Administration (FDA) approval of endometrial ablation devices includes only women for whom childbearing is complete.

**Regulatory Status**

The FDA indicates that endometrial devices are for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. FDA-approved devices for endometrial ablation include, but may not be limited to, laser therapy, electrical wire loop, rollerball using electric current, and thermal ablation using a liquid-filled balloon, microwave, electrode array, or a cryosurgical device. Examples of devices for endometrial ablation are:

- **The Hydro ThermAblator® system (Boston Scientific, Natick, MA):** This involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance. The Genesys HTA™ system (also Boston Scientific), a newer version of this technology that includes features such as a smaller console and simplified set-up requirements, was approved by the FDA in May 2010.

- **The Microwave Endometrial Ablation (MEA) system (Microsulis Medical, U.K.):** This delivers fixed-frequency microwave energy and may be performed in a physician’s office but does require use of the hysteroscope.

- **The ThermaChoice® device (J&J Ethicon Gynecare, Somerville, NJ):** This device ablates endometrial tissue by thermal energy heating of sterile injectable fluid within a silicone balloon. Endometrial ablation will only work when there is direct contact between the endometrial wall and the fluid-filled balloon. Therefore, patients with uteri of abnormal shape, resulting from tumors such as myomas or polyps, or large size, due to fibroids, are generally not considered candidates for this procedure.

- **The NovaSure™ impedance-controlled endometrial ablation system (Cytyc Corp, Marlborough, MA):** The system delivers RF energy to the endometrial surface. The device consists of an electrode array on a stretchable porous fabric that conforms to the endometrial surface.

- **Her Option™ Uterine Cryoablation Therapy™ system (American Medical Systems, Minnetonka, MN):** The system consists of, in part, a cryoprobe that is inserted through the cervix into the endometrial cavity. When cooled, an ice ball forms around the probe, which permanently destroys the endometrial tissue. Cryoablation is typically monitored by abdominal ultrasound.
Endometrial ablation, with or without hysteroscopic guidance, using an FDA-approved device may be considered **medically necessary** in women with menorrhagia who are not candidates for, or who are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Endometrial ablation is considered **investigational** for all other indications.

### Policy Guidelines

Intrauterine ablation or resection of the endometrium should not be confused with laparoscopic laser ablation of intraperitoneal endometriosis. This policy does not address laparoscopic intraperitoneal ablation.

Contraindications for intrauterine ablation or resection of the endometrium include:

- Patient who is pregnant or desires pregnancy.
- History of endometrial cancer or pre-cancerous histology.
- Patient with an active genital or urinary tract infection at the time of the procedure.
- Patient with active pelvic inflammatory disease.
- Patient with an intrauterine device (IUD) currently in place.
- Patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy.

Other contraindications for microwave ablation include Essure contraceptive micro-inserts in place, myometrial thickness less than 10 mm, and uterine sounding length less than 6 cm.

### Rationale

A review of the 1991 TEC Assessment concluded that endometrial ablation using either an Nd YAG laser or a resecting loop was an effective treatment of menorrhagia unresponsive to hormone treatment or dilation and curettage. (1) Since the 1991 TEC Assessment, additional devices have been introduced, and randomized studies supporting the use of these devices have been published.

### Comparison between endometrial ablation and hysterectomy

A 2012 systematic review of randomized controlled trials (RCTs) by Matteson and colleagues compared the efficacy of hysterectomy and less invasive techniques for controlling abnormal uterine bleeding. (2) The authors identified 9 trials directly comparing hysterectomy with another intervention and reporting health outcomes; 7 of these studies compared hysterectomy to endometrial ablation. The 7 studies included a total of 1,167 women, and follow-up ranged from 4 to 48 months. Due to the
heterogeneity of outcome measurement, study findings were not pooled. Following treatment, amenorrhea rates in the endometrial ablation groups ranged from 13-64% versus an implied 100% rate after hysterectomy. Five trials reported pain beyond the immediate post-operative period. The authors judged the quality of evidence on pain to be low but that results favored hysterectomy over ablation. Three studies reported that pelvic pain was less prevalent in the hysterectomy group than the ablation group; however, only one study compared rates statistically, and this study found a significantly lower rate of pain at 2-3 years’ follow-up in the group receiving hysterectomy. All 7 trials reported additional treatments obtained by participants after the initial intervention. At 1-4 years’ follow-up, the proportion of women in the ablation group who had an additional surgical procedure for bleeding was 16-42%; of these, 10-29% were treated with hysterectomy.

In 2011, the Health Technology Assessment (HTA) program in the U.K. conducted a meta-analysis of individual patient data from RCTs evaluating second-line treatments for menorrhagia. (3) They identified data on 1,127 women from 7 trials comparing first-generation devices to hysterectomy. A limitation of the review is that individual patient data were not available for approximately 35% of women randomized in the trials. The most frequently measured outcome in the studies was patient satisfaction/ dissatisfaction, and this was used as the primary outcome of the meta-analysis. After 12 months of follow-up, 7.3% (57/454) of women treated with first-generation endometrial ablation devices and 5.3% (23/432) of women who had a hysterectomy were dissatisfied with their treatment outcome. This difference was statistically significant, favoring hysterectomy (odds ratio [OR]: 2.46, 95% confidence interval [CI]: 1.54 to 3.93, p=0.0002).

In addition to the meta-analyses of data from published studies, the HTA included an analysis of individual patient data from national databases in Scotland to evaluate long-term outcomes after hysterectomy or endometrial ablation. The investigators identified a total of 37,120 women who underwent hysterectomy and 11,299 women who underwent endometrial ablation for dysfunctional uterine bleeding between 1989 and 2006. Women who received endometrial ablation were significantly older (mean of 42.5 years) compared to those receiving hysterectomy (mean of 41.0 years). The type of endometrial ablation device could not be determined. The median duration of follow-up was 6.2 years in the endometrial ablation group and 11.6 years in the hysterectomy group. During follow-up, 962 (8.5%) women who received endometrial ablation had additional gynecologic surgery compared to 1,446 (3.9%) women who had hysterectomy; this difference was statistically significant (adjusted hazard ratio [HR]: 3.56, 95% CI: 3.26-3.89). The most common types of additional surgery after endometrial ablation were intrauterine procedures (n=577, 5.1%) and repeat endometrial ablation (n=278, 2.5%). However, women who had initial endometrial ablation procedures were significantly less likely than those with initial hysterectomies to have surgery for pelvic floor repair (0.9% vs. 2.2%, respectively, adjusted HR: 0.50 to 0.77). Women were also less likely to have tension-free vaginal tape surgery for stress urinary incontinence after endometrial ablation than after hysterectomy (0.5% vs. 1.1%, respectively, adjusted HR: 0.55, 95% CI: 0.41 to 0.74).

Conclusion: The evidence suggests better outcomes (e.g., bleeding control, pelvic pain) and fewer additional surgeries in women who have hysterectomy compared to endometrial ablation. However, endometrial ablation is less invasive and involves retention of the uterus. Most of the studies comparing hysterectomy to endometrial ablation used first-generation techniques; there is less evidence comparing hysterectomy to second-generation techniques.
Comparison among different endometrial ablation methods

Numerous RCTs and several systematic reviews of RCTs have been published comparing different methods of endometrial ablation. Most recently, a 2012 review by Daniels and colleagues identified 14 trials comparing first- and second-generation methods and 5 trials comparing 2 second-generation methods of endometrial ablation for women with heavy menstrual bleeding who were unresponsive to medical therapy. (4) In their analysis, the investigators compared the efficacy of each pair of techniques; only a few comparisons included more than one trial. Eight studies compared a first-generation technique to thermal balloon ablation (total n=516). A pooled analysis of these studies did not find a significant difference in amenorrhea rates with the 2 types of techniques (OR: 0.72, 95% CI: 0.52-1.101). In addition, 3 studies compared the second-generation techniques, thermal balloon ablation and bipolar radiofrequency (RF) (total n=264). A pooled analysis showed a higher rate of amenorrhea with bipolar RF (OR: 4.56; 95% CI: 2.24-9.26).

A systematic review and meta-analysis by the Cochrane collaboration was published in 2009. (5) The review included RCTs that compared 2 ablation techniques and reported amenorrhea and patient satisfaction. A total of 21 studies with 3,395 premenopausal women were eligible for the review. Seven of the studies were multicenter (6 of these were based in the U.S.), and 14 were single center. Sixteen of the trials required women to have completed their families, 10 excluded women with fibroids, and 12 required that women had not tolerated or failed to respond to medical therapy. Only one trial required a dilation and curettage procedure prior to endometrial ablation. Five of the trials compared 2 first-generation ablation techniques. Two trials compared second generation techniques to one another, and the remaining 14 trials compared first- to second-generation procedures. There were only 1 or 2 studies on any given comparison of techniques; the exception was balloon ablation versus rollerball for which there were 3 studies (total n=352). A pooled analysis of these 3 studies found a statistically lower rate of amenorrhea at 1 year with rollerball than with balloon ablation (OR: 0.56; 95% CI: 0.33-0.96); the absolute rates of amenorrhea were 16% in the balloon ablation group and 24% in the rollerball group. However, there was not a significant difference in the satisfaction rate at 1 year (OR: 0.94; 95% CI: 0.44–1.99).

The investigators also compared first- and second-generation techniques. A pooled analysis of 12 studies (total n=2,085) did not find a significant difference in the rate of amenorrhea at 1 year (OR: 0.92; 95% CI: 0.62–1.37). The absolute rates of amenorrhea were 38% with first-generation procedures and 37% with second-generation procedures. Eleven studies reported satisfaction rates at 1 year, and there was not a significant difference between first- and second-generation techniques (OR: 1.20; 95% CI: 0.85–1.70). The absolute rates of satisfaction were high in both groups; 88% among those who received first-generation techniques and 91% among those who received second-generation techniques. In a pooled analysis of 7 studies (total n=1,058), there was no significant difference in the rate of additional surgeries within 1 year (OR: 0.74; 95% CI: 0.42–1.31). Data on fluid overload were available from 4 trials that compared first- and second-generation procedures. There was a total of 10/327 (3%) cases of fluid overload using first-generation techniques and 0/354 using second-generation techniques (OR: 0.17; 95% CI: 0.04 to 0.77). Compared to first-generation techniques, second-generation techniques were also associated with a significantly lower risk of perforation (OR: 0.32; 95% CI: 0.10 to 1.0), cervical lacerations (OR: 0.22; 95% CI: 0.08-0.6), and hematometra (OR: 0.31; 95% CI: 0.11 to 0.85). In contrast, second-generation techniques were associated with a significantly increased risk of nausea and vomiting (OR: 2.4; 95% CI: 1.6 to 3.9) and...
uterine cramping (OR: 1.8; 95% CI: 1.1 to 2.8). The meta-analysis did not find evidence of significant
differences in other complications rates or in secondary outcomes such as inability to work or need for
additional surgery or hysterectomy. The authors of the Cochrane review concluded that, overall, the
existing evidence suggests that success rates and complications profiles of second-generation
techniques compare favorably with the first-generation hysteroscopic techniques.

The 2011 assessment from the HTA, described above, also included comparisons of different
endometrial ablation methods. (3) The investigators identified data on 2,448 women from 14 trials
comparing first- and second-generation endometrial ablation devices. When first- and second-
generation endometrial ablation devices were compared, there was not a significant
difference between groups in the rate of amenorrhea after 12 months. When findings from 13 studies were
pooled, rates of amenorrhea were 326/899 (36%) with first-generation devices and 464/1,261 (37%)
with second-generation devices (OR: 1.12; 95% CI: 0.93 to 1.35). There were insufficient data to
conduct meta-analyses of longer-term amenorrhea rates. Similarly, the rates of menorrhagia after 12
months did not differ between groups. In a pooled analysis of 12 studies, rates were 111/899 (12.3%)
with first-generation devices and 151/1,281 (11.8%) after second-generation devices (pooled OR:
0.97, 95% CI: 0.74 to 1.28). In addition, a pooled analysis of 6 studies did not find a significant
difference in repeat endometrial ablations over 12 months after initial treatment with first-generation
devices (4/589, 0.7%) or second-generation devices (4/880, 0.5%) (OR: 0.71, 95% CI: 0.17 to 2.94).
The proportion of women requiring hysterectomy within 12 months after endometrial ablation did not
differ significantly when first-generation devices (39/933 [4.2%]) or second-generation devices
(35/1,343 [2.6%]) were used (OR: 0.77; 95% CI: 0.47 to 1.24 [11 studies]).

Representative RCTs with longer term follow-up are described below:

In 2009, Sambrook and colleagues published 10-year follow-up data from a U.K. study comparing
microwave endometrial ablation and transcervical resection of the endometrium. (6) The initial report
by Cooper and colleagues in 2005 found the 2 techniques to yield comparable results in terms of
menstrual status, satisfaction, acceptability of treatment, and health-related quality of life. (7) The
mean age at baseline was 42 years in the microwave group and 40 years in the resection group. After
10 years, study participants continued to report similar levels of satisfaction; 77/129 (60%) in the
microwave group and 70/134 (52%) in the transcervical resection of the endometrium (TCRE) group
reported being totally or generally satisfied with treatment. This difference was not statistically
significant. During the 10-year follow-up period, significantly more women in the resection group than
the microwave group received a hysterectomy (28% and 17%, respectively). Few participants, one in
the microwave group and 3 in the TCRE group, had repeat ablation procedures.

Kleijn and colleagues reported 5-year follow-up in 2008 of a study conducted in the Netherlands. (8)
After 1 year of follow-up, 43/81 (43%) of women who received biopolar radiofrequency (RF) ablation
and 3 of 39 (8%) in the balloon ablation group reported amenorrhea; this difference was statistically
significant [relative risk (RR): 6.8, 95% CI: 1.8 to 26]. (9) After 5 years, rates of amenorrhea were
39/81, (48%) in the RF ablation group and 12/39 (32%) in the balloon ablation group. The difference
between groups was not statistically significant at 5 years (RR: 1.7, 95% CI: 0.98 to 3.0). During the
follow-up period, 8 (10%) women in the RF group and 12 (13%) in the balloon ablation group received
a hysterectomy.
A 2010 study by Iglesias and colleagues attempted to identify which women are most likely to fail treatment with endometrial ablation. (10) This was a retrospective analysis of data on 142 women who were treated with hydrothermal ablation at a single institution. Patients had a median age of 40 years (range: 22–53 years) at the time of treatment. After a mean follow-up of 12 months, 97 women (68%) had a significant reduction in vaginal bleeding and were considered treatment successes, and the remaining 45 women (32%) were considered treatment failures. A total of 26 of the 142 women (18%) ultimately received a hysterectomy. Factors associated with treatment failure included younger age, tobacco use, and menometrorrhagia. Women who were at least age 45 years had a 16% treatment failure rate compared to a 38% rate in women younger than 45 years (p=0.014). The 35 women who smoked tobacco had a 46% treatment failure rate compared to a 27% failure rate in the 103 non-smokers (p=0.042). Sixty-five women reported menometrorrhagia and had a 42% treatment failure rate compared to the 75 women who reported only menorrhagia and had a 24% failure rate. Race (white versus other) and body mass index (BMI) (less than 30 or 30 and higher) were not significantly associated with treatment failure. These results have not been replicated in other studies.

Conclusion: There is no clear evidence that the net health benefit is superior with any method of endometrial ablation compared to any other method. Rates of menorrhagia and patient satisfaction were generally similar after treatment with first- and second-generation devices. Meta-analyses of the available data from RCTs suggest that there are higher rates of certain adverse events with first-generation techniques and higher rates of other adverse events with second-generation techniques.

Practice Guidelines and Position Statements

Society for Gynecologic Surgeons (SGS) systematic review group: In 2012, they published a clinical practice guideline on treatment of abnormal uterine bleeding. (11) The guideline recommends that, in women with bleeding caused mainly by ovulatory disorders or endometrial hemostatic disorders, any of the following treatments may be chosen depending on patient values and preferences: hysterectomy, endometrial ablation, systemic medical therapies or levonorgestrel-releasing intrauterine systems. In choosing between endometrial ablation and hysterectomy, if the patient’s preference is for amenorrhea, less pain or avoiding additional therapy, hysterectomy is suggested. If the patient’s preference is for lower operative and post-operative procedural risk, and a shorter hospital stay, endometrial ablation is recommended.

Practice Committee of the American Society for Reproductive Medicine (ASRM): In 2008, ASRM reviewed their 2006 Practice Committee report and reissued their statement on indications and options for endometrial ablation. (12) Conclusions were:

- “Endometrial ablation is an effective therapeutic option for the management of menorrhagia.
- Hysteroscopic and nonhysteroscopic techniques for endometrial ablation offer similar rates of symptom relief and patient satisfaction.
- Later definitive surgery may be required in 6% to 20% of women after endometrial ablation.
- Women who undergo hysterectomy after a failed endometrial ablation report significantly more satisfaction after 2 years of follow-up.
- Endometrial ablation generally is more effective when the endometrium is relatively thin.
• Ideally, hysteroscopic methods for endometrial ablation should be performed using a fluid monitoring system to reduce the risks and complications relating to fluid overload and electrolyte imbalance.

• Nonhysteroscopic methods for endometrial ablation require less skill and operating time."

American College of Obstetricians and Gynecologists (ACOG): In 2007, ACOG published a guideline on endometrial ablation. (13) Recommendations they assessed as being based on good and consistent evidence include:

• “For women with normal endometrial cavities, resectoscopic endometrial ablation and nonresectoscopic endometrial ablation systems appear to be equivalent with respect to successful reduction in menstrual flow and patient satisfaction at 1 year following index surgery.

• Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy. “

National Institute for Health and Clinical Excellence (NICE), United Kingdom: The 2007 NICE guidance on heavy menstrual bleeding includes the following recommendations regarding endometrial ablation (14):

• Endometrial ablation should be considered in women with heavy menstrual bleeding who have a normal uterus and those with small uterine fibroids (less than 3 cm in diameter).

• In women with heavy menstrual bleeding alone and a uterus no bigger than a 10-week pregnancy, endometrial ablation is preferable to hysterectomy.

• Endometrial ablation may be offered as an initial treatment for heavy menstrual bleeding after full discussion of the risks and benefits, and other treatment options.

• First generation techniques are appropriate if hysteroscopic myomectomy is to be included in the procedure.

• Second generation techniques that can be recommended include impedance-controlled bipolar radiofrequency ablation, fluid-filled thermal balloon endometrial ablation, microwave endometrial ablation and free fluid thermal endometrial ablation.

Summary

There is evidence from multiple randomized controlled trials that endometrial ablation improves the net health outcome in women who have failed prior treatment for menorrhagia and are otherwise eligible for hysterectomy. There is a lack of consistent evidence that any one ablation technique is superior to another. Thus, endometrial ablation using an FDA-approved device may be considered medically necessary in women with menorrhagia who have failed hormonal treatment and would be considered candidates for hysterectomy.
Endometrial ablation is considered not medically necessary for all other indications as reliable evidence does not exist that shows health benefits for the ablation procedure in other intrauterine maladies.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intrauterine ablation or resection of the endometrium for menorrhagia. TEC Evaluations 1991; p. 296-323.
7. Cooper KG, Bain C, Lawrie L et al. A randomised comparison of microwave endometrial ablation with transcervical resection of the endometrium; follow up at a minimum of five years. BJOG 2005; 112(4):470-5.
Policy History

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<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review. References 2, 4 and 11 added; other references renumbered or removed. No change to policy statements.</td>
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Keywords

Endometrial Ablation
Her Option™ Uterine Cryoablation Therapy™ System
Intrauterine Ablation
Laser Ablation of the Endometrium
Liquid-Filled Balloons Used in Endometrial Ablation
Rollerball Ablation of the Endometrium
TheraChoice
Hydro ThermAblator
Microwave endometrial ablation
The NovaSure

This policy was approved by the FEP Pharmacy and Therapeutics Committee on December 6, 2012 and is effective January 1, 2013.

Signature on file
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