Ultrasound-Guided Reoperative Hysteroscopy for Managing Global Endometrial Ablation Failures

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ABSTRACT

Study Objective: To determine whether ultrasound-guided reoperative hysteroscopy can reduce the need for hysterectomy in women experiencing delayed complications after global endometrial ablation (GEA) procedures.

Design: Retrospective review (Canadian Task Force classification III).

Setting: Private physician's office.

Patients: Fifty women who had experienced a delayed complication after a GEA procedure were referred to the author's private practice.

Intervention: All 50 women underwent ultrasound-guided reoperative hysteroscopy in which the uterine cavity was fully explored and areas of endometrial growth and other disease were identified and excised.

Measurements and Main Results: Intraoperative complications, patient satisfaction, and avoidance of hysterectomy were determined. There were no intraoperative or postoperative complications. The mean duration of follow-up was 18.1 months (95% confidence interval, 13.8–22.4). Forty-four of 49 patients (88.9%) were satisfied with the outcome, and further surgery was not necessary during the study period.

Conclusion: Ultrasound-guided reoperative hysteroscopy is a safe and effective minimally invasive treatment for management of delayed complications after GEA procedures. Journal of Minimally Invasive Gynecology (2014) 21, 238–244 © 2014 AAGL. All rights reserved.

Keywords: Abnormal uterine bleeding; Endometrial regrowth; Endometriometrial resection; Global ablation; Hematometra; Hysterectomy; Pelvic pain; Reoperative hysteroscopy

DISCUSS
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During the past two decades, endometrial ablation (EA) has been increasingly used in the management of abnormal uterine bleeding (AUB) refractory to medical treatment in women who have completed childbearing. In 1981, Goldrath et al [1] reported the first use of an Nd:YAG laser delivered via a quartz fiber passed through an operative hysteroscope. By 1989, the US Food and Drug Administration had granted approval to the first gynecologic resectoscope that incorporated inexpensive and readily available electrosurgical generators with continuous-flow sheaths [2]. Although there are no reliable estimates of the number of EAs performed using these early methods, it is clear that the second-generation techniques, also known as non-resectoscopic endometrial ablation or global techniques [3], enabled widespread adoption of EA. The first of 5 global endometrial ablation (GEA) devices appeared in 1997, and these are now extensively used throughout much of the developed world. In 2008 alone, some 312,000 GEA procedures were performed in the United States [4].

After EA, a substantial number of women eventually experience delayed complications that necessitate hysterectomy [5–8]. Longinotti et al [6] observed that 26% of 3681 women undergoing EA at 30 Kaiser Permanente Northern California facilities required hysterectomy during an 8-year follow-up. The 2007, the American College of Obstetricians and Gynecologists published a Practice Bulletin that stated that
hysterectomy rates within 4 years after both resectoscopic and GEA devices are at least 24% [8]. The late complications of EA are 3-fold: persistent or recurrent vaginal bleeding, cyclic pelvic pain, and inability to adequately assess the endometrium in women who later require sampling.

Recurrent and troublesome vaginal bleeding, may occur immediately or in the years after EA and has been attributed to inadequate endometrial destruction [9,10], unsuspected deep adenomyosis [11], or development of new disease such as myomas, endometrial hyperplasia, or cancer.

Cyclic pelvic pain may or may not be accompanied by vaginal bleeding and has been attributed to cornual and central hematometra [12] and post-ablation tubal sterilization syndrome [13]. McCausland and McCausland [12] noted that the cause of cyclic pelvic pain “following both resectoscopic and global procedures is due to the intrauterine scar-ring and contracture that can occur following the procedure.”

The inability to adequately assess the uterine cavity is another important and underreported delayed complication after EA and has been ascribed to formation of intrauterine scarring that obviates adequate endometrial sampling. Ahonkallio et al [14] established that endometrial biopsy failed in 23% of women with previous EA and was likely unreliable in many of the remaining patients in whom endometrium is often trapped in inaccessible intersites, often in cornual regions. Any of these delayed complications are sufficient reasons for hysterectomy.

Often reoperative hysteroscopic surgery (RHS) can forefend subsequent hysterectomy. In 1992, Gimpelson and Kaigh [15] reported a series of 16 women who underwent repeat EA via either hysteroscopic Nd:YAG laser or an electrosurgical technique; hystereccotomy was successfully avoided in all patients during the study. In a series of 118 women who were offered RHS, Istrate and Langebrekke [16] successfully averted hysterectomy in 72% of patients during a mean follow-up of 22 months. In 2001, Wortman and Daggett [17] reported a series of 26 women who had undergone sonographically guided RHS after EA failure, and hystereccotomy was avoided in 88.5% during a mean (SD) follow-up of 23.2 (22.7) months.

To our knowledge, this is the first report of a large series of women who have experienced delayed complications after a variety of GEA techniques and who have been managed using ultrasound-guided reoperative hysteroscopy (UGRH).

Material and Methods

Between April 1, 2004, and December 31, 2012, 50 women were seen in the private practice of one of us (M.W.) All had undergone 1 of 4 GEA procedures and had been referred for evaluation and management of delayed complications. All 50 patients underwent UGRH performed either in a hospital outpatient setting or in the aforementioned accredited office-based surgery practice.

The initial evaluation included a complete review of the patient’s history and medical records, as well as physical ex-

amination and transvaginal ultrasound performed by one of us (M.W.). Patients were carefully counseled about the risks, benefits, and alternatives to RHS.

In all patients, during the afternoon before surgery, laminaria insertion was accomplished with the adjuvant use of parenterally administered midazolam and fentanyl to achieve minimal sedation. In almost all instances, substantial stenosis was noted in the region of the internal cervical os and was overcome using a 2- to 3-mm Hegar dilator passed under sonographic guidance, followed by insertion of a 3- or 4-mm laminaria japonica. Women were asked to refrain from eating solid food for at least 4 hours before the office-based surgery and 8 hours before a procedure conducted in an ambulatory surgery center.

Equipment and Personnel

The equipment and personnel used for UGRH have been previously reported [18] and were identical to what is used for other sonographically guided hysteroscopic techniques [19]. Low-viscosity fluids were delivered via one of several fluid management systems. Our operating room is equipped with an Autocon II 400 (Karl Storz Endoscopy, Culver City, CA), enabling use of both unipolar and bipolar electrosurgery. Unipolar electrosurgery was generally performed at 140 W of C-Cut, effect 4, during the resection phase and 120 W of forced coagulation current, effect 4, for the coagulation portion of the procedure. When bipolar electrosurgery was used, a saline–C-Cut, effect 5, was used. During unipolar electrosurgery, 1.5% glycine was used for distention; normal saline solution was used during bipolar electrosurgery.

Nearly all procedures were performed using either a 22 F or a 26 F continuous-flow resectoscope. Sonographic guidance was provided in most cases via an Acuson X150 ultrasound system (Siemens Corp., Munich, Germany) equipped with a variable-frequency (2.5–5.0 MHz) abdominal transducer. Our operating room is equipped with 2 side-by-side monitors (Fig. 1) that facilitate real-time observation and coordination of personnel. All procedures are digitally recorded using a MediCapture USB 200 image capture device (MediCapture, Inc., Philadelphia, PA).

For office-based procedures, a minimum of 4 assistants were used: a first assistant, a sonographer, a fluid management technician, and an appropriately trained and creden-
tialed registered nurse who administered midazolam and fentanyl and monitored the patient’s level of consciousness and vital signs.

Procedure

For office-based procedures, patients were asked to arrive 30 minutes before the surgery and to not empty their bladder. After intravenous access was obtained, all patients were given either 2 g ampicillin intravenously or 300 mg clindamycin for prophylaxis. This was followed by a combination
of midazolam and fentanyl administered in small incremental doses at 3- to 5-minute intervals to achieve and maintain adequate sedation and analgesia. After removing the previously placed laminaria, the cervix and vagina were prepared using a bactericidal solution, after which 20 mL saline solution containing 2.5 U vasopressin was injected intracervically at the 3 and 9 o'clock positions. Mechanical dilation was performed to 8 or 10 mm under ultrasound guidance to accommodate either a 22 F or a 26 F unipolar resectoscope. Glycine, 1.5%, or normal saline solution was delivered at an infusion pressure of 120 to 180 mm Hg. Both the net and rate of fluid absorption were carefully monitored and never exceeded a calculated predetermined maximum allowable fluid absorption limit for glycine or saline solution [20,21].

**Approach to Tubular Cavity**

In most cases, initial hysteroscopy revealed a short tubular cavity, often with little or no obvious evidence of active endometrium (Fig. 2). These cavities, often containing abundant intrauterine synechiae, were generally associated with a longer latent period, the interval between the original GEA procedure and RHS. In the presence of a tubular cavity, women generally harbored coexisting cornual or central hematometra. In the absence of intraoperative sonographic evidence of hematometra, dissection was generally begun on the anterior or posterior uterine wall, whichever was thicker. Because continuous flow is often poor within a tubular cavity, the initial strip of tissue was generally removed relying solely on sonographic guidance, after which fluid egress was quickly established, enabling both excellent hysteroscopic and sonographic visualization. When the central hematometra (Fig. 3) lay adjacent to the tubular cavity, dissection was carried out into the hematometra, after which 3 to 5 mm tissue was removed beneath the basal layer of tissue that lined the cavity.

The goals of RHS were 3-fold: first, to establish a central cavity large enough to permit continuous flow of low-viscosity fluids; second, to proceed radially in all directions to explore the entire uterus to within 5 to 10 mm of its serosal surface; and third, to explore the cornual regions, including the tubal ostia if possible, within 2 to 4 mm of the serosa (Fig. 4).

Dynamic scanning, a combination of sagittal and transverse scanning, was performed to ascertain that the resectoscope was advanced in the midline of the uterus. This is especially important in the early portion of the procedure, when few if any landmarks are identifiable. This technique was especially important in advancing the loop electrode to within 10 mm of the serosal surface at the apex of the fundus. During resection of strips in the long axis, sagittal scanning was preferentially used to define the minimal distance between the operative site and the serosa of the anterior, posterior, and lateral walls. This technique was critical in women who had previously delivered via cesarean
section, whose lower uterine segment is often no more than 3 to 4 mm before reoperative surgery. Transverse scanning was primarily used to better visualize the minimum uterine wall thickness in the cornual regions and to enter hematometra lateral to the midline.

During the procedure, the uterine cavity was kept well distended to enable simultaneous dynamic sonohysterography throughout the entire procedure. This was accomplished by maintaining sufficient pump pressure and minimizing extravasation of fluid from the cervix and outflow port. Unlike endometrial resection [19], there was no predetermined order of resection. The variable hysteroscopic and sonographic findings in each procedure dictated the course of dissection, with the 2 views complementing each other.

Approach to Well-Developed Uterine Cavity

A well-developed cavity was often associated with a latent period of ≤6 months, frequently noted in women who reported little or no relief after undergoing the original GEA procedure. These cavities, often devoid of intrauterine synechiae, frequently contained submucous leiomyomas, large septums, or substantially enlarged uterine cavities, with sagittal dimensions >11 cm or transverse dimensions >8 cm.

Initial hysteroscopy often revealed a mixture of fibroconnective tissue and large areas of endometrium in one or more quadrants, along with other coexisting disease. Intrauterine synechiae, however, were often quite limited in this group, and a standard endometrial resection technique (Fig. 5) [19] was easily accomplished. In the presence of a previously unsuspected myoma, however, it was often necessary to remove the myoma before adequate uterine exploration was possible. The goal of RHS in this group was to resect all tissue to at least 4 mm beneath the basal layer of endometrium, a depth that was reduced to 2 to 3 mm at the cornua.

At the close of the procedure, whenever possible, deep coagulation of the myometrium was accomplished using either a 2- or 3-mm ball-end electrode at 120 W coagulation current. In many instances, it was not possible to perform this throughout the entire uterine cavity, in particular in areas in which only a thin seromucosal layer remained. All patients were observed for a minimum of 60 minutes after the procedure and were discharged when post-anesthesia recovery score as ≥9 [22].

Data Collection

Complete patient medical records were reviewed, including operative reports from GEA and RHS procedures. Patients were contacted via telephone or, in several cases, via e-mail. The women were asked whether they had experienced vaginal bleeding or cyclic pelvic pain. Oligomenorrhea was defined as the need to change a panty liner or minipad no more often than every 8 hours. Patients who experienced cyclic pain were asked to rate it on a 10-point scoring system, as follows: <4, mild; 4 to 7, moderate; and 8 to 10, severe. Operative and pathology reports were reviewed for women who had undergone hysterectomy.

Results

Fifty women underwent RHS between April 1, 2004, and December 31, 2012. Thirty-three women (66%) had previously received treatment via NovaSure (Hologic, Inc., Bedford, MA), 10 (20%) via HydroTherm Ablator (Boston Scientific, Inc., Freemont, CA), 6 (12%) via the Gynecare ThermaChoice Uterine Balloon Therapy System (Ethicon, Inc., Somerville, NJ), and 1 (2%) via the Her Option cryoendometrial ablation system (CooperSurgical, Inc., Trumbull, CT).

At the time of the reoperative procedure, mean patient age was 45.2 years (95% confidence interval [CI], 43.4–46.9). Mean interval between the GEA procedure and the onset of substantial symptoms was 12.8 months (95% CI, 6.8–18.7), and between the original GEA procedure and
RHS was 24.3 months (95% CI, 18.3–32.1). Forty-seven procedures (94%) were performed in an office-based setting, and 3 (6%) in an ambulatory surgical setting. The primary indications for RHS are given in Table 1.

In all 50 women, UGRH was successful; the uterine cavity was judged to be fully explored, and all areas of known endometrial growth and hematometra were identified and excised. No intraoperative or immediate postoperative complications occurred.

Mean operative time, measured from the first administration of intravenous sedation to completion of the procedure, was 35.9 minutes (95% CI, 32.5–39.4). Mean specimen weight was 11.7 g (95% CI, 9.0–14.3). One woman requested and underwent a concomitant Adiana procedure. Mean duration of follow-up was 18.1 months (95% CI, 13.8–22.4). Intraoperative findings are given in Table 2.

Sixty-one findings were recorded in 50 women. Ten percent of women were noted to have little discernible thermal effect as a result of the previous GEA procedure. The most common findings were the presence of submucous leiomyomas, ranging from 1.5 to 4 cm; a central cavity containing a hematometra accompanied by minimal fibrosis; and persistence of endometrial tissue in the uterine cornua.

Histologic findings in the 50 women are given in Table 3. Endometrial tissue was identified in 39 patients (78%). Eleven (22%) specimens contained submucous or intramural leiomyomas, and adenomyosis was identified in 8 specimens (16%).

Of the 50 women studied, 49 were contacted by either telephone or e-mail (Table 4). One patient was lost to follow-up. Forty women (80%) experienced no cyclic pelvic pain and achieved amenorrhea, oligomenorrhea, or occasional scant flow. Two women (4%) reported amenorrhea with mild cyclic pain, and another 2 (4%) reported amenorrhea with moderate cyclic pain.

Five women reported severe cyclic pain accompanied by either amenorrhea or oligomenorrhea; all were offered hysterectomy. Three elected to undergo laparoscopic hysterectomy, and 2 underwent a second UGRH procedure. Those 2 patients have been followed up for 4 and 26 months, respectively, and are presently free of symptoms. During the study, 44 of 49 patients (89.8%) did not require a second surgical procedure. Of the 5 women (10.2%) in whom a second surgery was required, 3 (6.8%) underwent hysterectomy.

Of the 3 hysterectomy specimens, 1 supracervical specimen weighed 40 g and revealed adenomyosis and inactive endometrium. A second uterus weighed 36 g and contained elements of proliferative endometrium and leiomyomas, with blood-filled cysts within the myometrium. The third hysterectomy specimen weighed 101 g and contained vascular ectasia and edema, focal adenomyosis, and some proliferative endometrium.

**Discussion**

GEA has emerged as an important and commonly used method for managing abnormal uterine bleeding in women who have completed childbearing and are not candidates for medical management. Only recently has the literature addressed the incidence of delayed complications subsequent

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**Table 2**

Intraoperative findings in 50 women undergoing reoperative hysteroscopic surgery and global endometrial ablation

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal anatomy, minimal or no effect</td>
<td>5 (10)</td>
</tr>
<tr>
<td>Uterine cavity with minimal fibrosis, central hematometra</td>
<td>14 (28)</td>
</tr>
<tr>
<td>Submucous leiomyoma</td>
<td>12 (24)</td>
</tr>
<tr>
<td>Tubular cavity</td>
<td>6 (12)</td>
</tr>
<tr>
<td>Uterine septae with untreated cornua</td>
<td>6 (12)</td>
</tr>
<tr>
<td>Untreated cornua</td>
<td>16 (32)</td>
</tr>
<tr>
<td>Cornual hematometra</td>
<td>2 (4)</td>
</tr>
</tbody>
</table>

**Table 3**

Histologic findings in 50 women undergoing reoperative hysteroscopic surgery after global endometrial ablation

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endometrium</td>
<td></td>
</tr>
<tr>
<td>Proliferative</td>
<td>22 (44)</td>
</tr>
<tr>
<td>Secretory</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Benign</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Inactive</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Menstrual</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Atrophic</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Disorderly</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Polyp</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Tubal endothelium</td>
<td></td>
</tr>
<tr>
<td>Metaplasia</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Myometrium</td>
<td></td>
</tr>
<tr>
<td>Leiomyoma</td>
<td>11 (22)</td>
</tr>
<tr>
<td>Adenomyosis</td>
<td>8 (16)</td>
</tr>
<tr>
<td>Hyalinized necrotic</td>
<td>4 (8)</td>
</tr>
<tr>
<td>Cauterized myometrial tissue</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Fibroelastosis</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>
to GEA procedures [5–8], which suggests that at least 25% of women will eventually require hysterectomy within 4 to 5 years. Longinotti et al [6] imply that the true incidence of hysterectomy subsequent to GEA has yet to be realized and will likely increase as data from longer follow-up become available.

Reducing the rate of subsequent hysterectomy after GEA procedures would seem to be a worthwhile endeavor requiring a 2-pronged approach: better patient selection and the appropriate use of RHS when appropriate. Patient selection criteria have been documented by several authors, who have described many factors associated with increased risk of GEA failure, primarily age <40 years [16] and presence of submucous [23,24] or intramural [25] leiomyomas. RHS, although described after hysteroscopic endometrial ablation and endometrial resection, has not been reported in a large series of women who experienced delayed complications of GEA. In 2001, Wortman and Daggett [17] reported excellent results in 26 women who required reoperative surgery after EA failure using UGRH; only 1 of these patients had undergone GEA. RHS was sufficient to avert hysterectomy in 88.5% of women during a mean (SD) follow-up of 23.2 (22.7) months.

Our present series, devoted exclusively to women who had previously undergone GEA, is relevant for 4 reasons. First, it provides some insight into why GEA failures occur. Nearly one-third of women were found to have intraoperative evidence of functioning endometrium at the uterine cornua. Clearly, the cornual regions are difficult to treat under ideal circumstances, in part because endometrium often resides deep within the isthmal portion of the fallopian tube [10]. However, this common intraoperative finding suggests that familiar anatomic distortions such as uterine septum and T-shaped uterus may limit exposure of the cornua to thermal energy and adversely affect patient outcome. The presence of submucous leiomyomas, present in nearly one-fourth of GEA failures, is another common finding in women who experience delayed complications.

Second, the present report demonstrates that UGHS can dramatically reduce the number of hysterecomies in women who have previously undergone GEA. In >88%, further intervention has thus far not been necessary after a single UGHS procedure. Although this number is expected to decline over time, it is encouraging. Given that the mean age of women undergoing RHS was 45.2 years, we are hopeful that most of these women will negotiate their menopausal years without the need for further surgery.

Third, UGHS seems to be safe. The use of sonographic guidance provides invaluable assistance in preventing uterine perforation in a setting that most would consider high risk for such an event. Although we do not believe that any current technique can entirely preclude uterine perforation, use of a noninvasive adjuvant such as ultrasound seems to offer considerable benefit.

Fourth, UGHS provides a histologic specimen. This is especially important for proper evaluation in women who experience postmenopausal bleeding and in whom ordinary endometrial biopsy provides an inadequate specimen [11,13].

Several limitations of the present study must be acknowledged. First, the duration of follow up was short. Longinotti et al [6] demonstrated that GEA outcomes deteriorate over time, and there is certainly every expectation that the number of women who have enjoyed a reprieve from hysterectomy will likely decrease over time. Second, the retrospective nature of the study is no substitute for a randomized control trial in treating GEA failures with hysterectomy vs UGRH.

In conclusion, UGRH is a safe and effective minimally invasive alternative to hysterectomy in women who have experienced a delayed complication of GEA. Although the short-term success in hysterectomy avoidance has been demonstrated, longer follow-up will be required to determine its eventual success. Mastery of this skill, however, requires considerable experience in standard resectoscopic techniques (endomyometrial resection and myomectomy) and the ability to work in concert with a highly proficient sonographer and operative team.

References

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