OBJECTIVE: To evaluate the accuracy of hysterosalpingography (HSG) in patients who underwent concomitant radiofrequency endometrial ablation and hysteroscopic sterilization.

METHODS: This historical cohort study was conducted at a midwestern academic medical center. A total of 186 women (94 with combined procedure and 92 with sterilization alone) were identified as having undergone intervention between January 1, 2003, and June 30, 2011. Two reviewers blinded to the surgical procedure interpreted the standard clinically indicated HSGs in each group.

RESULTS: The primary outcome assessed was the inability to rely on the microinserts for contraception based on HSG interpretation using manufacturers’ guidelines (unsatisfactory HSG). Position of the devices and occlusion of tubes were assessed on all 3-month and, when available, all 6-month repeat HSGs. At the 3-month HSG, 5 of 76 (6.6%, 95% confidence interval [CI] 2.2–14.7%) in the sterilization-only group had unsatisfactory HSG compared with 13 of 71 (18.3%, 95% CI 10.1–29.3%) in the combined group ($P = .03$).

After accounting for the seven patients who underwent repeat HSG at 6 months, 3 of 76 (3.95%, 95% CI 0.8–11.1%) in the sterilization-only group had unsatisfactory HSG compared with 13 of 71 (18.31%, 95% CI 10.1–29.3%) in the combined group ($P = .005$).

CONCLUSION: After completing all clinically indicated HSGs, patients who undergo concomitant radiofrequency endometrial ablation and hysteroscopic sterilization have an approximate fivefold increase (odds ratio 5.45, 95% CI 1.48–20.0) in the rate of unsatisfactory HSG for purposes of documenting tubal occlusion.

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LEVEL OF EVIDENCE: II

Endometrial ablation is a safe and effective treatment for heavy menstrual bleeding but is contraindicated in patients who desire fertility potential.¹ Pregnancies after endometrial ablation are possible with an estimated incidence between 0.7% and 1.6%²–⁵ and tend to be high risk.³,⁴ Sterilization procedures are often recommended concurrently with ablation. Hysteroscopic sterilization performed concomitantly with endometrial ablation has been described.⁶–¹⁰

Both the U.S. Food and Drug Administration (FDA) and the American College of Obstetricians and Gynecologists (the College) recommend performing hysterosalpingography (HSG) 3 months after hysteroscopic sterilization.¹¹,¹² The purpose of HSG is to document device presence, device position, and tubal occlusion before relying on the devices for contraception. Although other countries rely on radiography or ultrasonography as the primary follow-up test, many include HSG as the definitive test for indeterminate results.
Endometrial ablation is known to result in the formation of uterine synechiae.\textsuperscript{13,14} This may negatively affect the quality and accuracy of HSG. Current manufacturer instructions advise against performing radiofrequency endometrial ablation at the time of hysteroscopic sterilization.\textsuperscript{12,15} College Committee Opinion No. 458 advises against performing these procedures at the same time.\textsuperscript{11} Based on the results in a preliminary feasibility study,\textsuperscript{6} we felt performing endometrial ablation would have a minor effect on the ability to perform or interpret HSG. The aim of our study was to critically evaluate and quantify the effects of endometrial ablation on the ability to perform and interpret HSG in the setting of a concomitant procedure.

MATERIALS AND METHODS

This study was approved by the Mayo Clinic institutional review board. The study cohort was initially established to assess the feasibility and safety of the combined procedure. Women included in the study were pursuing treatment for heavy menstrual bleeding with radiofrequency endometrial ablation, requesting permanent sterilization between January 1, 2003, and June 30, 2011. Only women who provided their authorization for use of their medical records in research were included in the study. The study is written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement.\textsuperscript{16}

We searched the electronic medical record for all combined procedures occurring during the study period. The combined treatment cohort consisted of patients who underwent radiofrequency endometrial ablation using the NovaSure device followed immediately by hysteroscopic sterilization with Essure (microinsert devices). Patients were documented to have heavy menstrual bleeding and desired permanent sterilization. After thorough counseling by one of our four minimally invasive gynecologic surgeons (M.R.H., A.O.F., D.M.B., S.K.L.-T.), they elected to proceed with the combined procedure. Subsequent to FDA labeling changes and the release of the College Committee Opinion, performance of the procedure was restricted to those patients whose medical comorbidities and clinical situation favored a concomitant approach. Patients were advised as to the off-label nature of this approach. Combined procedures were performed in an operating room under intravenous sedation or in the office using nonsteroidal anti-inflammatory drugs and, if necessary, a paracervical block. For both cohorts, patients were instructed to use a reliable form of contraception for 3 months postprocedure. Follow-up HSGs were ordered for 3 months postprocedure. In cases of unsatisfactory 3-month HSG, a follow-up 6-month postprocedure HSG was performed. Clinical data abstracted from the medical record included basic demographic information, prior cesarean delivery, need for subsequent hysterectomy, and postprocedure pregnancy.

A radiologist (D.J.W.) interpreted stored HSG images to assess the primary outcome: the inability to rely on the microinserts for contraception based on HSG interpretation using manufacturers’ guidelines. A gynecologist’s (D.J.C.) interpretation of the same images was used to assess variability between the observers. Both reviewers were blinded to the procedure performed. The HSGs were evaluated for the following: device presence, device position, tubal occlusion, cornual opacification, and uterine cavity appearance. Device position and tubal occlusion were graded using a three-grade system as described in the Essure Physician Training Manual and outlined by Wittmer et al.\textsuperscript{17,18} For position, grade 1 is defined as an insertion that has been expelled or has more than 50% of the inner coil protruding into the uterine cavity (proximal placement). Grade 2 is satisfactory position. Grade 3 describes an insertion with the proximal end of...
the inner coil greater than 30 mm from the uterine cornua or expelled into the abdominal cavity (distal placement). With respect to occlusion, grade 1 indicates that the fallopian tube is occluded at the cornu. Grade 2 indicates that contrast material is seen in the tube but not past any portion of the outer coil of the microinsert. Grade 3 indicates that contrast material is seen past a portion of the outer coil of the microinsert or in the peritoneal cavity. The HSGs were interpreted as satisfactory if position was grade 2 and occlusion was grade 1 or grade 2. In patients in whom the initial HSG was unsatisfactory because of patency (grade 3 occlusion), a repeat HSG was performed 3 months after the initial HSG.

For secondary outcomes, the uterine cavity was evaluated for opacification by contrast agent using HSG. We developed a five-grade system to describe the presence and degree of intrauterine synechiae. Grade 1 indicates the absence of synechiae in which 100% of the uterine cavity fills with contrast. Grade 2 indicates the presence of some synechiae in which greater than 75% of the uterine cavity fills with contrast; similarly, grade 3 indicates 25–75% of the cavity fills, grade 4 less than 25% of the cavity fills, and grade 5 indicates complete obliteration of the uterine cavity by synechiae. Each image of the uterine cornua was evaluated for opacification by contrast.

For categorical variables, comparisons were conducted with \( \chi^2 \) or Fisher’s exact test as needed. For continuous variables, mean and standard deviation were used for presenting normally distributed variables; median and range were used for skewed data. The independent \( t \) test and Wilcoxon rank-sum were used for comparisons among continuous variables. The agreement between the two observers (D.J.W. and D.J.C.) for tubal position and occlusion was assessed using \( \kappa \) for the cohort and stratified by procedure group with significance testing done using McNemar’s test. All analyses were performed using STATA 10.0. All tests were two-sided; \( P < .05 \) was considered statistically significant.

**RESULTS**

During the study period, 93 patients were identified as having undergone a combined procedure. We randomly selected 93 patients who underwent hysteroscopic sterilization during the same period. A patient in the latter group was found to have undergone a combined procedure and was reassigned to the combined group leaving 94 and 92 patients, respectively. A proportion of patients (18.3%) in the overall study cohort did not have a 3-month HSG performed, most commonly as a result of noncompliance; HSGs were not completed in 14 of 92 (15.2%) patients in the sterilization-only group compared with 20 of 94 (21.3%) patients in the combined group (\( P = .3 \)). Of note, one patient in the combined group had cervical stenosis and one had severe discomfort that precluded completion of the HSG; there were no patient-related reasons for incomplete HSG in the sterilization-only group. Five additional patients completed the HSG, but stored images were inadequate for evaluation by study personnel. This resulted in a final study cohort including 76 patients in the sterilization-only group and 71 in the combined group (Fig. 1). There were no differences in bilateral placement rate of the devices at the time of the procedure (\( P = .6 \)). Patient demographics were similar between the groups except women in the combined group were older and more likely to have a history of prior cesarean delivery (Table 1).

The combined group had 13 of 71 (18.3%, 95% confidence interval [CI] 10.1–29.3%) HSGs interpreted as inadequate compared with 5 of 76 (6.6%, 95% CI 2.2–14.7%) in the sterilization-only group at the time of the initial 3-month HSG (\( P = .03 \)). Women in the combined group were approximately three times more likely to have an unsatisfactory HSG at 3 months with an odds ratio (OR) of 3.18 (95% CI 1.07–9.45). Seven patients underwent repeat HSG: two in the sterilization-only group and five in the combined group. All HSGs were unsatisfactory as a result of tubal patency. The HSGs of both patients in the sterilization-only group were satisfactory at 6 months. None of the repeat HSGs were satisfactory in the combined group; three because of persistent patency and two because of synechiae. After including all completed HSGs, 3 of 76 (3.95%, 95% CI 0.8–11.1%) patients in the sterilization-only group had unsatisfactory HSG compared with 13 of 71 (18.3%, 95% CI 10.1–29.3%) in the combined group (\( P = .005 \)). Women in the combined group were approximately five times more likely to have an unsatisfactory HSG when 6-month repeat HSGs were included (OR 5.45, 95% CI 1.48–20.0) (Table 2).

Total agreement between reviewers for diagnosing unsatisfactory HSG was 133 of 147 (90.5%) with a \( \kappa \) of 0.481, which is interpreted as moderate agreement. Agreement was statistically significantly higher in the sterilization-only group with total agreement in 73 of 76 (96.1%) with a \( \kappa \) of 0.551 compared with total agreement in 60 of 71 (84.5%) in the combined group with \( \kappa \) of 0.431 (\( P = .03 \)).

When the uterine cavity was assessed for opacification by contrast dye, we found 19 of 76 (25%) patients with sterilization-only had some evidence of
synechiae compared with 57 of 71 (80.3%) patients in the combined group (P<.001). Table 3 outlines the degrees of synechiae demonstrated in the two groups. When the left uterine cornua was assessed independently, lack of opacification by contrast dye was documented in 1 of 76 (1.3%) patients in the sterilization-only group compared with 5 of 71 (7%) in the combined group (P<.02). For the right uterine cornua, lack of opacification was 0 of 76 (0%) in the sterilization-only group and 4 of 71 (5.6%) in the combined group (P=.05).

For clinical outcomes, in the overall cohort (n=186), we identified 14 of 186 (7.5%) patients who underwent subsequent hysterectomy; 4 of 92 (4.4%) were in the sterilization-only group and 10 of 94 (10.6%) were in the combined group (P=.1 data not shown). The indications for hysterectomy were: abnormal uterine bleeding and pain (n=3), abnormal uterine bleeding (n=2), pain (n=1), symptomatic fibroids (n=3), prolapse (n=1), cervical adenocarcinoma in situ (n=1), endometrial adenocarcinoma (n=1), prophylactic (n=1), and persistently elevated human chorionic gonadotropin (n=1). In the study cohort with available HSG (n=147), we identified 9 of 147 (6.1%) patients who underwent subsequent hysterectomy; 4 of 76 (5.3%) were in the sterilization-only group and 5 of 71 (7.0%) in the combined group (P=.7). One postprocedure intrauterine pregnancy was identified in the combined group, which occurred 44 months postprocedure. A left tubal patency at the 3-month HSG led to a repeat HSG at 6 months at which time there was no intraperitoneal spill of dye but the HSG was unsatisfactory resulting from uterine synechiae. This patient presented with an incomplete abortion and underwent dilatation and curettage with laparoscopic salpingectomy to rule out ectopic pregnancy. Pathology reports supported the diagnosis of an intrauterine pregnancy. Postoperatively she had a persistently elevated hCG and ultimately underwent hysterectomy.

Fig. 1. Study flowchart.
Table 1. Comparison of Women Who Underwent Either Microinsert Hysteroscopic Sterilization Only or Sterilization Combined With Radiofrequency Endometrial Ablation for Whom Hysterosalpingogram Images Were Available for Review

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sterilization Only (n=76)</th>
<th>Combined (n=71)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at procedure (y)</td>
<td>36.89±6.21</td>
<td>40.01±5.68</td>
<td>.002*</td>
</tr>
<tr>
<td>Gravidity</td>
<td>2 (0–7)</td>
<td>3 (0–10)</td>
<td>.3†</td>
</tr>
<tr>
<td>Parity</td>
<td>2 (0–5)</td>
<td>2 (0–6)</td>
<td>.7‡</td>
</tr>
<tr>
<td>History of cesarean delivery</td>
<td>7 (9.2)</td>
<td>24 (33.8)</td>
<td>&lt;.001‡</td>
</tr>
<tr>
<td>Subsequent hysterectomy</td>
<td>4 (5.3)</td>
<td>5 (7.04)</td>
<td>.7‡</td>
</tr>
<tr>
<td>Bilateral placement</td>
<td>73 (96.1)</td>
<td>70 (98.6)</td>
<td>.6‡</td>
</tr>
<tr>
<td>Subsequent pregnancy</td>
<td>0 (0)</td>
<td>1 (1.4)</td>
<td>.5‡</td>
</tr>
</tbody>
</table>

Data are mean±standard deviation, median (range), or n (%).†Wilcoxon rank-sum.‡Wilcoxon rank-sum.

DISCUSSION

Concerns regarding the effects of endometrial ablation on the requisite confirmatory HSG have influenced FDA labeling and a College Committee Opinion. Our previous experience suggested the effect on the HSG would be minimal. Although other studies have focused primarily on the safety and feasibility of the combined procedure; our study specifically evaluated the interpretation of HSG after radiofrequency endometrial ablation.

We found 18.3% of patients in the combined group were unable to rely on their devices for contraception based on the interpretation of the HSG. Levy-Zauberman et al assessed the position of hysteroscopically placed microinserts after concomitant endometrial destruction in 106 patients using pelvic radiography, three-dimensional ultrasonography, HSG, or any combination of the three. In their study, 15.1% of microinserts were reported as “uncertain” and 3.8% were reported as “inadequate,” whereas 81% of patients with combined procedures were “successful.”

Mircea et al reported on 87 patients who underwent concomitant radiofrequency endometrial ablation and hysteroscopic sterilization. Only 21 patients in their study underwent follow-up testing with HSG; of these, five were reported to have synechiae. Interestingly, of the five patients with synechiae, three had unsatisfactory HSG as a result of inadequate fill of the uterine cavity with contrast media. Their resultant 3 of 21 (14.2%) unsatisfactory HSG rate is similar to our findings. Other methods of confirmatory testing included pelvic radiography and pelvic ultrasonography.

The theoretical pregnancy rate is presumed to be very low (0.0032%) after a combined endometrial ablation and hysteroscopic sterilization. This is based on the assumption that pregnancies occur in 1.6% of ovulating women after global endometrial ablation and combining this with the 0.2% 5-year failure rate of microinsert hysteroscopic sterilization. Although our study was not powered to evaluate postprocedure pregnancy, the circumstances of the pregnancy that occurred in the study timeframe are consistent with data regarding unintended pregnancies after hysteroscopic sterilization.

Although alternative imaging modalities (radiography, transvaginal ultrasonography) are being evaluated in determining reliance on microinsert hysteroscopic sterilization for contraception, they do not assess tubal patency. Rather, they document the presence and proper position of the devices and presume occlusion for contraceptive purposes. Interestingly, using HSG, Rodriguez et al found 90- and 180-day tubal patency rates of 16.1% and 5.8%, respectively, after hysteroscopic sterilization without any reported pregnancies. This raises the question as to the clinical relevance of documenting tubal occlusion. Thus, it is unclear if the nearly fivefold increased rate of inadequate HSG found in our study confers an increased risk of hysteroscopic sterilization failure when combined with an ablation procedure.

The primary reason for unsatisfactory HSGs was the presence of synechiae and lack of opacification of the uterine cornua. As a result, contrast cannot adequately

Table 2. Comparison of Unsatisfactory Hysterosalpingogram at 3 and 6 Months

<table>
<thead>
<tr>
<th>HSG</th>
<th>Sterilization Only (n=76)</th>
<th>Combined (n=71)</th>
<th>P*</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mo</td>
<td>5 (6.6, 2.2–14.7)</td>
<td>13 (18.3, 10.1–29.3)</td>
<td>.03</td>
<td>3.18 (1.07–9.45)</td>
</tr>
<tr>
<td>6 mo</td>
<td>3 (3.9, 0.8–11.1)</td>
<td>13 (18.3, 10.1–29.3)</td>
<td>.005</td>
<td>5.45 (1.48–20.0)</td>
</tr>
</tbody>
</table>

HSG, hysterosalpingogram; OR, odds ratio; CI, confidence interval. Data are n (%), 95% CI unless otherwise specified.

*Wilcoxon rank-sum.
reach the cornual regions to document the tubes are occluded. Our finding of 80% of patients with some degree of uterine synechiae in the combined group contrasts with the 23.8% (5/21) uterine synechiae rate seen in the Mircea et al study; this may be attributed to a different grading scale of uterine synechiae in our study. Alternatively, our routine use of suction curettage compared with its use in only 27% of patients in Mircea et al may explain the difference as well. The high proportion (25%) of HSGs with uterine synechiae in our study after sterilization only highlights the importance of appropriate comparison groups.

When comparing agreement between the two independent observers we found, although agreement was characterized overall as moderate, the agreement was significantly higher in the sterilization-only group compared with the combined group. The presence of synechiae appears to increase the variability in HSG interpretation; further studies are needed to assess this.

The strengths of our study include the interpretation of HSGs by independent, blinded observers using standardized, validated criteria. Conversely, the retrospective nature of this study does provide some limitations. Mainly, stored HSG images are not as ideal as prospective, real-time evaluation of images during HSG. We lost several patients to follow-up for either noncompliance or having an inadequate number of stored images. Our overall noncompliance rate for performance of the HSG (18%) is within the range previously reported in the literature.27,28

Our data demonstrate more uterine synechiae, higher rates of unsatisfactory HSG, and less intraobserver agreement on HSG interpretation in the combined group.

Presently, our data provide specific risk quantification in judging the effect of a concomitant procedure on HSG interpretation and the subsequent ability to rely on hysteroscopic sterilization for contraception as is currently mandated by the FDA and endorsed by the College.

### Table 3. Comparison of Extent of Intrauterine Synechiae Between the Cohorts

<table>
<thead>
<tr>
<th>% of Uterine Cavity Opaquefied With Contrast (Grade)</th>
<th>Sterilization Only (n=76)</th>
<th>Combined (n=71)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 (1)</td>
<td>57 (75)</td>
<td>14 (19.7)</td>
<td>&lt;.001*</td>
</tr>
<tr>
<td>More than 75 (2)</td>
<td>18 (23.7)</td>
<td>37 (52.1)</td>
<td></td>
</tr>
<tr>
<td>25–75 (3)</td>
<td>1 (1.3)</td>
<td>18 (25.4)</td>
<td></td>
</tr>
<tr>
<td>Less than 25 (4)</td>
<td>0</td>
<td>2 (2.8)</td>
<td></td>
</tr>
<tr>
<td>0 (5)</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Data are n (%) unless otherwise specified. * χ², comparison between groups.

## REFERENCES


