Hysteroscopic Sterilization Device Follow-Up Rate: Hysterosalpingogram versus Transvaginal Ultrasound

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Each author has indicated that he or she has met the journal’s requirements for authorship. The manuscript represents original research that has not been published or presented in part or whole.

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Patient compliance with 3 month confirmation testing after Essure hysteroscopic sterilization was increased with transvaginal ultrasound versus hysterosalpingogram.

Abstract

Study Objective: To assess if follow-up confirmation testing 3 months after hysteroscopic sterilization with the Essure device improved with recommendation for transvaginal ultrasound (TVUS) versus hysterosalpingogram (HSG).

Design: Retrospective, observational case-controlled cohort study (Canadian Task Force classification II-2)

Setting: Two physician private practice in Evansville, Indiana

Patients Compliance rates for a TVUS confirmation test on 100 women who underwent hysteroscopic sterilization compared to a previously published cohort of 1004 women who were scheduled to undergo HSG confirmation test.

Intervention: Acquisition of 3 month confirmation testing after Essure hysteroscopic sterilization

Measurement and Main Results: All women who underwent Essure hysteroscopic sterilization with recommendation for TVUS confirmation testing between July 2015 and January 2017 were compared to a previously published cohort of 1004 patients with recommendation for HSG confirmation testing (HSG cohort). In addition, an HSG subgroup cohort (HSG subgroup) similar in size and closest chronology to the TVUS cohort was drawn from the original 1004 patients and analyzed for HSG follow-up. Records for all patients were reviewed for demographic, procedural, confirmation testing, and outcome data. One hundred patients were identified with successful Essure device placement and a recommendation for TVUS confirmation testing.

Eighty-eight (88.0%) patients returned for TVUS at 3 months. In the HSG cohort, 1004 successful Essure devices were placed and 778 patients returned for the recommended HSG follow-up.
follow-up (77.5%). There was a significantly higher follow-up rate for TVUS compared to the HSG cohort (88.0% vs 77.5%, p = 0.008). In the HSG subgroup, 184 patients were identified and 133 patients presented for HSG follow-up (72.3%) indicating a significantly higher follow-up rate in the TVUS cohort (88.0% vs 72.3%, p = 0.001). No pregnancies after any confirmation testing were noted.

**Conclusion:** Confirmation testing with transvaginal ultrasound rather than hysterosalpingogram 3 months after Essure device placement results in increased patient compliance that may lead to improved patient outcomes with reduction of unintended pregnancy.

**Keywords:** Essure; Hysterosalpingogram; Hysteroscopic sterilization; Transvaginal ultrasound
Introduction

Sterilization is the most commonly used form of contraception among women in the United States (US). The only Food and Drug Administration (FDA) approved hysteroscopic method involves placement of an Essure device to induce fallopian tube occlusion. The Essure micro-insert is a spring-like device that consists of a stainless steel inner coil, a nickel titanium (nitinol) expanding outer coil, and polyethylene terephthalate (PET) fibers that are wound in and around the inner coil. Benefits to hysteroscopic sterilization are the ability to perform the procedure in the office setting reducing cost, avoiding intra-abdominal surgery and general anesthesia, and shorter recovery times.

A disadvantage of Essure is that it requires women to undergo radiologic imaging three months after the procedure to ensure proper device location and/or tubal occlusion before the procedure can be relied upon for pregnancy prevention. Prior to 2015, the only approved confirmatory test was a modified hysterosalpingogram (HSG) and follow-up rates are reported to vary between 13% to 92%. Unfortunately, studies have shown failure to complete confirmation testing increases risk for unintended pregnancies. In July 2015, the FDA approved transvaginal ultrasound (TVUS) as an alternative method for confirmation in appropriately selected individuals (Figure 1).

Although TVUS has been widely utilized in non-US countries with no increase in pregnancy rates, TVUS has not been widely adopted in the US and little data exist to detail its use in this population. In addition, availability of the Essure device has been reduced worldwide magnifying the need to evaluate the least invasive methods of confirmation testing in the US population. In October 2015, one private practice in Indiana began recommending TVUS for confirmation testing. The purpose of this study is to assess whether follow-up confirmation testing rates at three months after Essure hysteroscopic sterilization improved with recommendation for TVUS over HSG.
Methods

A retrospective, observational case-controlled cohort study was undertaken to evaluate women who underwent hysteroscopic sterilization with the Essure device with recommendation for transvaginal ultrasound confirmation testing between July 2015 and January 2017 at a single private practice in a suburban setting in southern Indiana. All patients scheduled for an Essure procedure during this time period with either of two physicians at this practice were included in the study. This time period was selected because TVUS confirmation of Essure was first FDA approved in July 2015 and prior to July 1, 2015 all patients who had the procedure performed were recommended to undergo HSG as the sole confirmatory test. Data were collected on patient age at time of procedure, gravidity, parity, length of procedure, pain during procedure, number of trailing coils, compliance with recommended confirmatory TVUS or HSG, and any subsequent procedures performed post-sterilization.

A previously published dataset from the same private practice recording outcomes of Essure sterilization in 1024 patients was used as the HSG comparison data (HSG cohort). The HSG dataset evaluated all patients who had an attempted Essure procedure between January 2006 and March 2014 with similar data collection utilized for the current study. Compliance rates for confirmation HSG rather than TVUS were recorded in this dataset as HSG was the only approved confirmation test for Essure during this time period.

The HSG cohort was collected over a much longer timeframe than the TVUS cohort resulting in an unbalanced study design. To address the possibility that differences in follow-up or counseling practices could be related to this, an HSG subgroup was obtained that spanned a similar time frame as the TVUS cohort. A subgroup of patients undergoing the Essure procedure in the 81-week period before April 15, 2014 was also analyzed to compare follow-up rates between HSG and TVUS over a time period of similar duration with minimal separation in time between collection periods (HSG subgroup).
The FDA has mandated specific training for practitioners and ultrasonographers to perform TVUS Essure confirmation testing and is offered through Bayer, Inc. Criteria for TVUS confirmation testing eligibility after the Essure procedure include: no uterine perforation during procedure, easily identified bilateral tubal ostia, certainty of bilateral placement with no concern for tubal perforation such as loss of resistance or use of excessive force during placement, procedure lasts less than 15 minutes total (scope in, scope out), only 1-8 trailing coils, no unusual post-operative pain, and patient is not on immunosuppressive therapy. The private practice was certified prior to performing any TVUS exam for this study and utilized a General Electric Voluson P8 3D/4D ultrasound machine. All images were captured with a transvaginal probe. Ultrasound images were obtained and recorded in accordance with recommendations and include the following: documentation of uterus orientation in the midline sagittal view and non-visualization of either insert (scout image); identification of two inserts in the oblique transverse view with no noted contact between the two devices and noted linear axis of devices are symmetrical and traversing the interstitial portion of the fallopian tubes; focused views of bilateral corneal areas with noted linear axis of insert identified as a contiguous echogenic structure. All of the aforementioned images were captured with 2D imaging. All images are reviewed by physician for meeting criteria for patient to rely. Greater than 99% of HSG exams were performed in an outpatient radiology facility by board certified radiologists. A modified low pressure HSG utilizing a 7 French/29cm balloon HSG catheter was performed on a majority of patients. Radiologists would interpret all images for device location and tubal occlusion and send reports to the office. The surgeon placing the Essure devices would review all reports and determine if patients could rely or need further counseling.

All patients scheduled for either HSG or TVUS 3 month confirmation test were given appointments for these exams on the day of their procedure. All patients received a phone call or text from the private practice reminding the patients of the scheduled HSG or TVUS within 1-
3 days prior. If a patient did not present for HSG exam, the practice received a notification from the radiology department and all patients were attempted to be contacted to reschedule the exam. If a patient did not present for TVUS, the practice attempted to contact all patients to reschedule the exam. All patients were informed of coverage for both the Essure procedure and confirmation test prior to scheduling.

The in-office anesthesia protocol for the Essure procedure evolved over time, with the majority of patients receiving mild oral sedation, anxiolytic non-sedating doses of intravenous (IV) fentanyl and/or versed, IV ketorolac, and a paracervical block of either 10 cc of 0.5% ripovocaine/20cc of 1% lidocaine/30 cc of saline or 20 cc of 1% lidocaine. Pain was recorded on a scale of 0 to 10 with the patient being instructed that a zero level would indicate no pain and a level of 10 would represent cramping associated with labor. Pain was recorded immediately after the procedure was completed and the patient was asked to designate a pain level at the time of highest pain during the procedure. A 5mm Bettocchi hysteroscopic system was utilized for all procedures with warmed saline solution as the distention media on pressure up to 100 to 200 mmHg with either speculum assistance or vaginoscopy.

The HSG cohort, HSG subgroup, and TVUS cohort follow-up rates were analyzed with chi-squared tests. Demographic information on the HSG cohort and TVUS cohort was compared using Wilcoxon–Mann–Whitney and chi-squared tests where appropriate. Post hoc chi-square tests evaluated the influence of significantly different demographic data on follow-up rates for the combined HSG full and TVUS cohorts. A p-value of less than 0.05 was considered significant for all tests. The Institutional Review Board at Indiana University School of Medicine approved the study as an exempt protocol.

**Results**

A total of 109 patients were identified as scheduled for an Essure procedure during the study period. Of these, 9 patients were excluded from the TVUS follow-up evaluation group. One Jeirath et al. *Hysteroscopic Sterilization Follow-up Rates*
patient had a hysterectomy for abnormal uterine bleeding due to leiomyomata prior to her 3 month follow-up and another had a bilateral salpingectomy before her 3 month follow-up after a pre-ablation ultrasound revealed a suspected perforated Essure device. Three patients opted for alternate contraception after failed bilateral Essure placements, and 4 patients were recommended to undergo HSG due to the number of trailing coils at the time of procedure. Of the 4 patients advised to undergo HSG testing, all presented for follow-up with 3 patients noted to have bilateral satisfactory location and one patient to have a right Essure coil noted to be outside of the tube and abdominally located.

In total, 100 patients were identified as having a successful bilateral or planned unilateral Essure placement and recommended to undergo TVUS confirmatory testing (Figure 2). Ninety-eight patients underwent successful bilateral placement and met TVUS criteria. Two patients were included in the analysis who had intended unilateral Essure placement secondary to previously known and documented unilateral salpingectomy for ectopic pregnancy.

Of the 100 patients recommended to undergo TVUS confirmatory testing, 88 presented for appropriate follow-up (88.0%). Twelve patients did not receive a 3-month confirmatory ultrasound as recommended. However, of those 12 patients, ten had a TVUS prior to a subsequent in-office ablation within the first 3 months after their Essure. All patients were noted to have satisfactory location of bilateral Essure devices and patients were informed of these results. These patients were counseled to return for the scheduled 3-month follow-up Essure TVUS but did not return. Two patients had Essure placement only but received no follow-up imaging; One patient was contacted after failing to present for 3 month TVUS and declined to reschedule and one patient did not return phone calls. All 12 patients were contacted to reschedule the missed TVUS exam with some patients declining to be rescheduled and others did not return messages for rescheduling.
In the HSG cohort, 1004 patients had a successful bilateral Essure device placement and 778 patients returned for the recommended HSG follow-up (77.5%). There was a significantly higher follow-up rate for TVUS compared to HSG (88.0% vs 77.5%, p = 0.008).

In the HSG subgroup that was analyzed over a similar timeframe to the TVUS group, 184 patients were included and 133 patients presented for HSG follow-up (72.3%) indicating a significantly higher follow-up rate in the TVUS cohort compared to the HSG subgroup (88.0% vs 72.3%, p = 0.001) (Table 1).

No statistically significant difference was observed between patient age, gravidity, parity, or procedure time between the two groups (Table 2). However, the number of trailing coils and procedural pain rates were found to be statistically significant between the TVUS and HSG cohorts. To further evaluate this data, post-hoc chi-square tests were utilized to assess if these factors influenced follow-up. The number of trailing coils on the left and right were higher in the TVUS cohort than the HSG cohort (p < 0.001) but this difference did not affect follow-up rates (coils 0–3: follow-up 78.4%, 4–8: 80.3%, >9: 69.2% and 0–3: 78.3%, 4–8: 78.1%, >9: 77.4%; p = 0.243 and p = 0.496, respectively). Conversely, higher pain ratings were associated with a lower follow-up rate (pain 0–2: follow-up rate 78.3%, 3–4: 75.0%, 5–6: 82.1%, 7–8: 82.5%, 9–10: 47.6%; p = 0.004). This effect was driven by low follow-up rates for patients that rated pain as either a 9 or 10. An average pain score of 9-10 in the TVUS cohort was reported over 4.5 times more frequently than in the HSG cohort (TVUS: 9.18% vs HSG: 1.89%); however, only 2.9% of the study population was in this category. Despite the negative effect of pain on return rates, more women obtained a 3 month TVUS compared to HSG.

Being a large referral gynecology only practice, many of the patients at this practice underwent an Essure device placement as a form of permanent contraception prior to an endometrial ablation for treatment of heavy menstrual bleeding. In the TVUS cohort, 66 of 100 patients who underwent a successful Essure procedure had a subsequent endometrial ablation (66.0%).

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was similar to the HSG cohort where 626 had an ablation after the Essure procedure (62.4%, p = 0.286). Similar percentages of patients in each group also underwent hysterectomy after Essure for varying reasons (TVUS 4.0%, HSG 6.3%, p = 0.290). No pregnancies in the TVUS or HSG cohorts were reported in any patient with successful bilateral or planned unilateral Essure placement regardless of confirmatory testing method.

Discussion

In this study, confirmation testing with transvaginal ultrasound versus hysterosalpingogram 3 months after Essure placement resulted in increased patient compliance. Based on previously reported data, this increased compliance will likely lead to improved patient outcome due to decrease risk of unplanned pregnancy.\(^9\,^{14}\)

Essure is an effective and well accepted procedure for permanent contraception with a failure rate at 5–10 years of 0.15%–0.96%.\(^9\,^{14}\) In a worldwide review of post-Essure pregnancies, Munro et al. reported that 35% of pregnancies were associated with lack of confirmation testing.\(^14\) Given the clear benefits of confirmation testing in preventing unintended pregnancies after Essure, approaches that promote follow-up will be beneficial to patients. Some reported strategies include prescheduling confirmation testing, placing reminder calls, and pre-determining insurance coverage for confirmation testing.\(^7\) As demonstrated by this study, an additional strategy may be the adoption of TVUS as a first line confirmatory test in appropriately qualified patients.

In this cohort, all patients that were counseled to undergo HSG testing due to disqualifying factors for a TVUS confirmation test were compliant in obtaining the HSG exam. This was likely due to more stringent counseling of patients to obtain HSG when they do not qualify for TVUS. Disqualifying factors include a more difficult procedure, non-optimal coil count during the procedure, or uncharacteristic pain noted by the patient before or after the procedure. These criteria may serve to better identify the most at risk patients for device malplacement and thus Jeirath et al.

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pregnancy risk can be more extensively counseled with TVUS exclusion criteria and requiring closer follow-up.

Some physicians have concerns that TVUS confirmatory testing does not demonstrate occlusion and therefore are reluctant to adopt this method. Interestingly, HSG has a reported false positive rate for bilateral occlusion as high as 39% and thus, demonstration of occlusion does not guarantee occluded tubes. In this study, no pregnancies from Essure device failure were reported in either the HSG or TVUS cohorts; although the TVUS pregnancy data has a shorter amount of follow-up as compared to the HSG cohort. Nonetheless, these results are consistent with other studies documenting no statistically significant differences in Essure failure rates when utilizing HSG or TVUS. The one year effectiveness rate of TVUS in a recent FDA trial was noted to be 0.67% and was consistent with known effectiveness rates in patients undergoing HSG for confirmation testing.

In this study, the reported pain between the TVUS and HSG cohorts was statistically significant and noted to be higher in the TVUS cohort (p<0.0001). Furthermore, higher pain levels were noted to be associated with lower follow-up rates. This represented a paradoxical result in that a greater proportion of patients returned for TVUS despite having a higher pain level during the procedure over the HSG cohort. There are two likely explanations for the differences in pain reported during the Essure procedure between the HSG and TVUS cohorts. One is the in-office anesthesia protocol evolved over time with overall decreasing utilization of IV pain medications during the procedure. The HSG cohort represented a time frame from 2006-2014 while the TVUS cohort occurred from 2015 to 2016. Secondarily, an additional physician performed the Essure procedure in the TVUS cohort. In the HSG cohort, one physician performed all the procedures utilizing a lidocaine/neuropin paracervical block and continued use of this block in the TVUS cohort. The additional physician included in the TVUS cohort utilized a lidocaine only block and patients receiving the lidocaine only block typically reported higher pain. Despite the higher pain score in the TVUS group compared to the HSG group, more women obtained a 3 Jeirath et al. Hysteroscopic Sterilization Follow-up Rates
month TVUS compared to HSG indicating that the negative effect of pain was small compared to a larger positive effect of TVUS on patient compliance.

TVUS offers other clinical advantages over the modified HSG. TVUS is a less invasive form of testing resulting in decreased patient pain and infection with no patient exposure to radiation. Additionally, TVUS can be performed in the office setting increasing satisfaction for many patients by providing convenience, cost effectiveness, and anxiety reduction by avoiding a more invasive procedure in an unfamiliar healthcare setting.

A notable strength of this study is the opportunity to have both cohorts from the same practice allowing for a strong statistical control. Demographic information between the groups was comparable with no statistically significant differences. In addition, patients had similar rates of subsequent procedures following their Essure procedure including ablation and hysterectomy. There are several limitations to this study. A confounding factor is that some patients in both cohorts underwent an early TVUS (between 0-89 days post-Essure) prior to a planned endometrial ablation procedure with noted satisfactory location of Essure devices. Many of these patients did not return for their scheduled 3 month confirmatory test suggesting these patients may not have understood the continued need for the 3 month follow-up TVUS or HSG.

Furthermore, a majority of this cohort is privately insured and may not represent outcomes in other patient populations. Lastly, in this study all patients undergoing TVUS confirmation testing completed the imaging in the same office where the Essure procedure was performed. It is uncertain if the follow-up rates would be similar if patients were sent to an outside facility to obtain the 3 month TVUS.

Due to the recent FDA approval of TVUS confirmation testing, little short-term or long-term data is available in the US population. Further studies are encouraged to understand the benefits and risks of this confirmation testing modality. In our study, confirmation testing with transvaginal ultrasound versus hysterosalpingogram 3 months after Essure device placement results in
increased patient compliance that may lead to improved patient outcomes with reduction of unintended pregnancy.

References


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Figure 1  Criteria for Transvaginal Ultrasound Confirmation Testing after Essure*

- No uterine perforation
- Easily identified bilateral tubal ostia
- Certain of bilateral placement
- Procedure lasts less than 15 minutes total
- Only 1-8 trailing coils
- No unusual post-operative pain
- Patient is not on immunosuppressive therapy

*All criteria must be met to offer transvaginal US in lieu of HSG for confirmatory testing. All physicians and ultrasonographers must be appropriately trained to perform and interpret TVUS with Essure prior to utilizing this method for confirmation. (5)

Figure 2  Essure TVUS Cohort Flowchart

TVUS, Transvaginal Ultrasound; HSG, Hysterosalpingogram

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Table 1: Confirmatory Testing Follow-Up

<table>
<thead>
<tr>
<th></th>
<th>Follow-Up (#)</th>
<th>No Follow-Up (#)</th>
<th>Follow-Up Rate (%)</th>
<th>p-value compared to TVUS</th>
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</thead>
<tbody>
<tr>
<td>TVUS</td>
<td>88</td>
<td>12</td>
<td>88.0</td>
<td>-</td>
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<tr>
<td>HSG cohort</td>
<td>778</td>
<td>226</td>
<td>77.5</td>
<td>0.011</td>
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<tr>
<td>HSG subgroup</td>
<td>133</td>
<td>51</td>
<td>72.3</td>
<td>0.002</td>
</tr>
</tbody>
</table>

TVUS, transvaginal ultrasound; HSG, hysterosalpingogram

Table 2: Demographic and Procedural Variables for TVUS and HSG Cohorts

<table>
<thead>
<tr>
<th></th>
<th>TVUS Cohort</th>
<th>HSG Cohort</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>38.7 ± 6.4</td>
<td>37.8 ± 6.2</td>
<td>0.2368</td>
</tr>
<tr>
<td>Gravidity</td>
<td>2.0 ± 1.5</td>
<td>1.8 ± 1.2</td>
<td>0.3089</td>
</tr>
<tr>
<td>Parity</td>
<td>1.7 ± 1.1</td>
<td>1.6 ± 1.1</td>
<td>0.4902</td>
</tr>
<tr>
<td>Procedure Time (minutes)</td>
<td>4.9 ± 4.8</td>
<td>4.8 ± 5.0</td>
<td>0.7183</td>
</tr>
<tr>
<td>Patient Reported Pain</td>
<td>3.9 ± 3.0</td>
<td>2.1 ± 2.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Trailing Coils on Right</td>
<td>2.7 ± 2.2</td>
<td>1.8 ± 2.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Trailing Coils on Left</td>
<td>3.4 ± 3.0</td>
<td>2.0 ± 2.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subsequent Ablation</td>
<td>66.0%</td>
<td>62.4%</td>
<td>0.3798</td>
</tr>
<tr>
<td>Subsequent Hysterectomy</td>
<td>4.1%</td>
<td>6.3%</td>
<td>0.3158</td>
</tr>
</tbody>
</table>

Data reported as mean ± standard deviations or percentages.

TVUS, transvaginal ultrasound; HSG, hysterosalpingogram

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