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# Contraceptive failure after hysteroscopic sterilization: Analysis of clinical and demographic data from 103 unplanned pregnancies

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**Objective**
This investigation examined data on unplanned pregnancies following hysteroscopic sterilization (HS).

**Methods**
A confidential questionnaire was used to collect data from women with medically confirmed pregnancy (n=103) registered after undergoing HS.

**Results**
Mean (±SD) patient age and body mass index (BMI) were 29.5±4.6 years and 27.7±6.1 kg/m$^2$, respectively. Peak pregnancy incidence was reported at 10 months after HS, although <3% of unplanned pregnancies occurred within the first three months following HS. Mean (±SD) interval between HS and pregnancy was 19.6±14.9 (range, 2 to 84) months. Patients age ≥30 years and BMI <25 reported conception after HS somewhat sooner than younger patients, although the differences in time to pregnancy were not significant (*P*=0.24 and 0.09, respectively). The recommended post-HS hysterosalpingogram (to confirm proper placement and bilateral tubal occlusion) was obtained by 66% (68/103) of respondents.

**Conclusion**
This report is the first to provide patient-derived data on contraceptive failures after HS. While adherence to back-up contraception 3 months after HS can be poor, many unintended pregnancies with HS occur long after the interval when alternate contraceptive is required. Many patients who obtain HS appear to ignore the manufacturer's guidance regarding the post-procedure hysterosalpingogram to confirm proper device placement, although limited insurance coverage likely contributes to this problem. The greatest number of unplanned pregnancies occurred 10 months after HS, but some unplanned pregnancies were reported up to 7 years later. Age, BMI, or surgical history are unlikely to predict contraceptive failure with HS. Further follow-up studies are planned to capture additional data on this issue.

Keywords: Contraception; Contraceptive failure; Essure; Pregnancy

## Introduction

Each year, more than 300,000 women request permanent surgical sterilization in the United States [1], and laparoscopic bilateral tubal ligation remains the most widely used operative approach to achieve this. However, in 2002 a non-incisional technique became available for bilateral tubal occlusion via hysteroscopic placement of metal inserts at the utero-tubal junction. Hysteroscopic sterilization (HS) brings several advantages over standard laparoscopy by eliminating the need for

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abdominal access [2,3], reducing overall cost [4], and minimizing anesthesia requirements [5]. The only HS method currently available is Essure (Bayer HealthCare AG, Whippany, NJ, USA) which was the focus of the current study. While latex free, the HS implants do contain acrylonitrile butadiene styrene, polytetrafluoroethylene polyvinyl pyrrolidone, polyethylene terephthalate and nickel, among other components [6].

Worldwide, at least 750,000 women have undergone HS and this contraceptive method is reported to be safe and effective [7,8]. In France, government health authorities recommend HS as the "first line alternative" for women over age 40 who request permanent contraception [9]. Even its off-label use in the management of hydrosalpinges (before *in vitro* fertilization and embryo transfer) has been mostly favorably reported [10]. Efficacy data provided by the device manufacturer claims that HS is 99.83% effective at preventing pregnancy over a five year interval, with the proviso that the implant is only used for approved indications and according to "perfect use" guidelines [11]. However, a recent investigation [12] questioned several aspects of the prior reports and, crucially, presented a very different efficacy assessment of HS. Using an evidence-based Markov model to estimate pregnancy rates among HS users over a 10 year interval, pregnancy probability at year 1 and over 10 years was found to be substantially higher with HS compared to laparoscopic sterilization [12]. Disagreement on contraceptive efficacy notwithstanding, the lay press has called attention to serious safety concerns associated with HS [13], thus underscoring the urgent need for more data on this contraceptive method. Moreover, clinical experience with HS remains somewhat limited as the total worldwide output of Essure publications is currently less than 200 despite more than a decade of clinical use. Against this background, the current analysis aimed to improve the understanding of HS by offering descriptive information collected directly from Essure patients who experienced an unintended pregnancy after undergoing this contraceptive procedure.

## Materials and methods

A multi-item research questionnaire was developed specifically for women who had a medically confirmed pregnancy following HS with Essure. Queries were structured to permit numerical or text responses (Table 1) and then configured electronically for an internet interface. The sample consisted of women who had already joined a closed, invitation-only support group for patients who underwent HS and had at least one subsequent unplanned pregnancy. Although participants were required to register via computer to access the questionnaire site, there was no cost to do so and respondents received nothing of value in exchange for their responses.

Participation in this investigation was open to all members of a support group (n=115), itself a subsidiary of the closed, web-based "Essure Problems" patient education and advocacy group (n=16,772) which is currently the world's largest comprehensive internet resource for Essure patients (https://www.facebook.com/groups/Essureproblems/). The questionnaire was posted in English and maintained on a dedicated internet site for a five week period, beginning February 6, 2015. Incomplete questionnaires were excluded and responses were electronically tracked to block duplicate submissions from the same individual. Height and weight information was received from participants either in Imperial (US) or SI (Système International, metric) units, with automated metric conversion for analysis. Only investigators had access to running totals of the questionnaire during the study.

This study proposal was submitted to an independent ethics committee prior to questionnaire implementation. Because the investigation tabulated data in an anonymous, non-identifiable manner and involved no direct contact with study participants, the research protocol was judged as "no risk to human subjects" and exempted from review.

### 1. Statistical analysis

Patient data were aggregated, analyzed, and visualized with MATLAB R2015a (Mathworks, Natick, MA, USA) and Tableau 9.0 (Tableau Software, Seattle, WA, USA). To estimate various proportions, the Maximum Likelihood Estimation was used. The proportions' confidence intervals were derived with the Adjusted Wald Method when necessary. For all analyses, the confidence level was set at 95% by default unless otherwise specified. The patients' age, body mass index (BMI), interval from HS to pregnancy, and number of pregnancies were all skewed right in their distributions. Log transformation was applied to these variables when the statistical analysis required a normal distribution assumption. The Pearson's chi-squared test was used for comparisons between two proportions. For comparisons of two sample means, the Welch two sample *t*-test was used and the sample sizes were further confirmed to be large (>30). In analyzing the probability distribution of the

**Table 1.** Patient questionnaire used to obtain information from individuals reporting unplanned pregnancy after undergoing hysteroscopic sterilization (n=103)

| | |
|---|---|
| 1. | In what year were you born? |
| 2. | What was your highest level of education completed when you underwent the HS procedure? |
| 3. | What is your highest completed level of education now? |
| 4. | How would you describe your race/ethnicity? |
| 5. | In what year did you have Essure implants placed? |
| 6. | As you were considering HS, were you given literature by your doctor describing the procedure? |
| 7. | As you were considering HS, did you consider the printed materials provided to be helpful and informative? |
| 8. | As you were considering HS, were you given an opportunity to ask questions about the procedure? |
| 9. | As you were considering HS, what other birth control methods were you thinking about before deciding on Essure? |
| 10. | As you were considering HS, what role, if any, did your partner/spouse/significant other play in your decision? |
| 11. | As you were considering HS, were you specifically counseled about the device containing polyethylene terephthalate fibers? |
| 12. | As you were considering HS, was the potential for nickel allergy/sensitivity discussed? |
| 13. | If you can recall, did you have to pay anything out of pocket to have HS? |
| 14. | If you can recall, did your insurance cover the cost to have HS? |
| 15. | Did your physician indicate that they had been specifically trained in the Essure procedure? |
| 16. | How many times had you been pregnant when you had HS? |
| 17. | When you had HS, had you ever had an autoimmune diagnosis of any kind? |
| 18. | What was your approximate height and weight when you had HS? |
| 19. | Has there been any change in your weight since HS? |
| 20. | If yes, please describe. |
| 21. | How many total pregnancies (including miscarriages & abortions) did you have at the time of HS? |
| 22. | How many total deliveries (livebirths) did you have at the time of HS? |
| 23. | At the time of your HS, were you married? |
| 24. | Since HS, has your marital status changed or do you have a new partner? |
| 25. | At the time of HS, were you a smoker? |
| 26. | Since HS, has your smoking status changed? |
| 27. | At the time of HS, had you ever had any abdominal or pelvic surgery? |
| 28. | If yes, please list. |
| 29. | After HS, did you ever have abdominal or pelvic surgery of any kind? |
| 30. | If yes, please list. |
| 31. | After HS, did you have an X-ray (hysterosalpingogram) to confirm that the device was placed properly? |
| 32. | If not, please explain why this was not done. |
| 33. | If yes, did your doctor discuss the findings (of the X-ray) with you? |
| 34. | If yes, did insurance pay for the confirmatory X-ray? |
| 35. | During the 3 months after HS, did you use a 'back up' method of birth control? |
| 36. | If yes, what kind and for how long? |
| 37. | How long after HS was pregnancy confirmed? |
| 38. | Since you had HS, have you ever used fertility medications of any kind? |
| 39. | Did you carry the pregnancy (with Essure in place) to term and delivery? |
| 40. | If yes, what type of delivery (vaginal or cesarean section)? |
| 41. | What was your baby's birthweight and sex? |

HS, hysteroscopic sterilization (Essure procedure).

interval from HS to pregnancy, the Maximum Likelihood Estimation with Generalized Extreme Value distribution [14] was used to generate the fitted probability density function and the fitted cumulative distribution function.

## Results

### 1. Study sample and demographic features

The total number of women with unplanned pregnancy after HS (support group members) fluctuated upward somewhat during the study interval, although the closed group reached maximum membership (n=115) near the close of the investigation. Completed questionnaires were returned from 103 women (mean±SD age, 29.5±4.6 years), representing a response rate of 89.6%. A random audit was conducted on a representative subset of respondents (n=12) to verify 1) that HS had been performed and document the date of the Essure procedure, and 2) that a positive pregnancy test was recorded after HS.

Among participants, 94 of 103 (91.3%) were self-identified as white/Caucasian. Few women (9.7%) in this group had less than a high school education at time of sterilization, while 44.7% had completed at least two years of college. After undergoing the HS procedure, 13.6% (14/103) of this sample obtained further education. Most (57.3%) study subjects were married at the time of HS, and 71 of 103 (68.9%) were still with the same significant other (either non-married partner or legal spouse) at time of survey. Two of 59 married patients (3.4%) divorced after HS and three of 103 (2.9%) were never married or never had a significant other/partner.

Most patients in this sample had private health coverage at time of their HS, and 88 of 103 (85.4%) indicated that their insurance fully paid for HS. In contrast, coverage for the post-HS confirmatory HSG was only available for 50.5% (52 of 103) patients. Only 17 of 103 (16.5%) of respondents reported having offset any expense associated with HS "out-of-pocket." The recommended hysterosalpingogram (HSG) after HS was obtained by 66% (68 of 103) of women in this group.

### 2. Clinical characteristics

In this sample, mean (±SD) interval between the HS procedure and positive pregnancy test was 19.6±14.9 (range, 2 to 84) months, although peak incidence (mode) for pregnancy was recorded 10 months after HS. Only three of 103 unplanned pregnancies (2.9%) occurred within the initial three months following HS. Fifteen patients (14.6%) reported an ongoing pregnancy at time of survey. Cumulative probability of pregnancy is shown in Fig. 1. Younger patients (age <30 years) who underwent HS had unplanned pregnancy slightly later than patients age ≥30 years, although this difference was not significant ($P$=0.68). At time of survey, mean±SD BMI was reported as 27.7±6.1 kg/m$^2$ for this group. While weight gain after HS was reported by 81.6% (84 of 103) of women, the time interval between HS and unplanned pregnancy was somewhat longer for those with BMI ≥25 compared to those with BMI <25 (21.1±13.7 vs. 17.6±16.1 months, $P$=0.09).

In addition, the sample was stratified according to history of prior pelvic or abdominal surgery. Analysis of these sub-groups

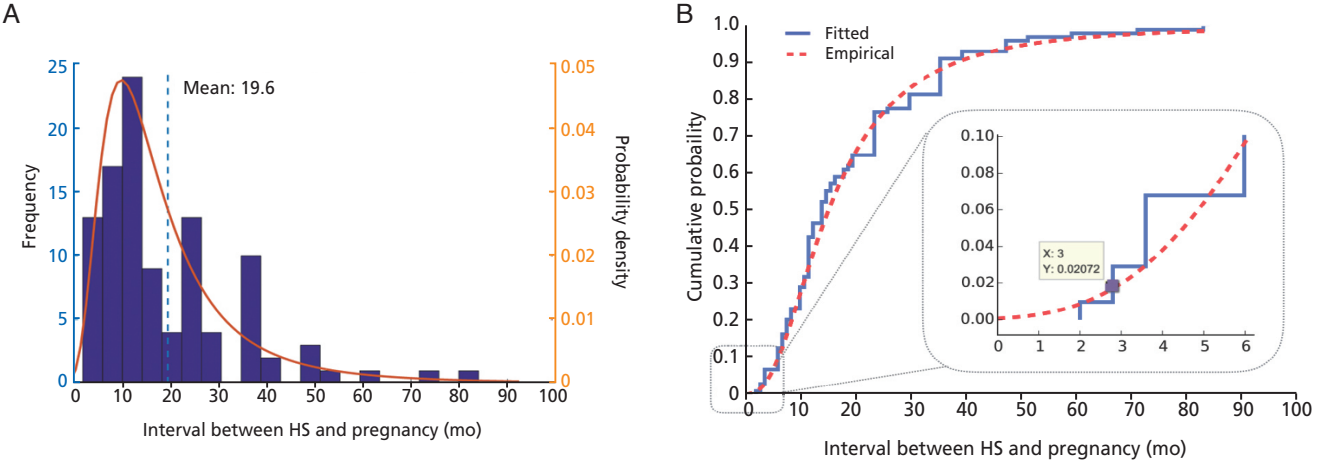


**Fig. 1.** (A) Probability density of interval to pregnancy after hysteroscopic sterilization (HS) as reported in 103 unplanned pregnancies. (B) Cumulative probability of interval to pregnancy following HS in months. Conceptions recorded during the first three months following HS reflect the observation that most (97.1%) unplanned pregnancies occurred later than 3 months after HS (inset).

found that although women without previous surgery (n=66) outnumbered those with prior instrumentation (n=37) in this population, there was no significant difference in pregnancy interval subsequent to HS (20.1±16.3 vs. 18.8 ±12.2 months, respectively; *P*=0.83). Most (66%) of our population were non-smokers at time of HS. Comparing smoking status before vs. after HS, this remained unchanged for the majority (87.4%) of women. Indeed, 9 of 35 (25.7%) smokers quit after undergoing HS, and among the 68 non-smokers at baseline, four (5.9%) became smokers after HS.

In this population, patients reported a total of 3.6±2.6 pregnancies (and 2.4±1.3 deliveries) before HS. From the 103 unplanned pregnancies after HS, 55 (53.4%) had a live birth delivery, 33 (32%) did not deliver, and 14.6% were pregnant at time of survey. When HS was being initially considered by these patients, 91 of 103 (88.4%) were undecided and open to other birth control options. The most common alternative contraceptive methods under consideration included laparoscopic tubal ligation (74.8%), partner vasectomy (21.4%), and oral contraceptive pills (9.7%). The partner's role or input was reported as "an important influence" in selecting HS by 67 of 103 (65.1%) respondents.

Regarding use of a back-up method of birth control during the three months immediately following HS, 73.8% (76 of 103) were compliant. While less than half (51 of 103, 49.5%) of HS patients received literature from their doctor describing HS before the procedure, among those who did, most (86.3%) found this information helpful. During pre-procedure counseling, 9 of 103 (8.7%) respondents indicated that they were advised that the HS implant contained nickel and the potential existed for hypersensitivity or allergy to this metal. Three of 103 (2.9%) patients were specifically informed about the HS implant containing polyethylene terephthalate fibers. Nevertheless, 86.4% (89 of 10) participants recalled having "plenty of time to ask questions" before undergoing the procedure. Only 4 of 103 (3.9%) of study participants had ever been diagnosed with any autoimmune condition, either before or after HS. Of note, 41 of 103 (39.8%) of patients reported that the physician who placed their contraceptive coils indicated special training with HS.

## Discussion

HS has been available to patients in the United States since 2002, although this is the first study to gather data directly from women with an unplanned pregnancy while using this method of birth control. Our analysis contributes to a larger understanding of HS by extending the observations of previous studies, while also challenging some others. For example, this analysis supports the findings of prior investigators who have noted reduced contraceptive efficacy when a method requires multiple steps (such as Essure) compared to simpler, single-step methods like intrauterine devices and contraceptive implants [12,15]. The current data align with this observation as patient compliance with the use of a "back up" birth control method (for three months immediately following HS) was only 73.8%, and the rate of follow-up with the required HSG after HS was even worse at 66%. Because this study group was educated (>40% had at least two years college) and most had access to insurance (>85% had private health coverage), it is difficult to identify specific characteristics that might explain this low self-reported adherence.

To date, studies on patient compliance with the post-HS HSG have been limited and have reported variable results [16]. Specifically, during clinical trials for HS patient compliance with post-placement HSG was very high, exceeding 90% [17]. Insured patients have been reported to have good adherence rates for keeping their HSG appointment [18] although lower income women may have a post-HS HSG compliance rate below 20% [19]. Not surprisingly, clinics that place a nurse in charge of scheduling HSG appointments for HS patients, calling them with appointment reminders, and tracking HSG compliance will have a significantly better HSG follow-up rate, compared with no outreach effort [20]. A retrospective cohort study of 638 patients who had HS over a six-year period [21] reported that 57% of HS procedures were performed in an operating room (not in a doctor's office), but observed no association between success in bilateral device placement or occlusion and any patient characteristic, irrespective of the clinical setting (hospital vs. office). However, their investigation acknowledged that private insurance, patient age, and performance of HS in the office setting were positively associated with likelihood of compliance with post-HS hysterosalpingography [21]. Other investigators have found that not speaking English or having to travel large distances are not associated with "no show" status at the post-HS HSG appointment to confirm proper placement [16]. While all of our study participants were English-speaking, we were unable to assess distance traveled for HSG or the possible role of economic status

in our sample, as these parameters were not collected in our study. No clinical data on post-HSG counseling following HS have yet been published, and indeed for those women in our study group who did comply with the HSG three months after HS, we do not know if the radiograph confirmed bilateral tubal occlusion or not.

Our information on prior smoking status (and change in smoking status subsequent to HS), prior abdominal/pelvic instrumentation, and total number of pregnancies (and deliveries) before HS, joins observations from other reports in describing features of HS patients. This study also supplies original data regarding what types of birth control were being contemplated by patients when their choice for HS was made, as well as the role of a husband/partner on a woman's decision to undergo HS. It is hoped that future research will include these parameters going forward.

This evaluation has some limitations which should be acknowledged. For example, the internet-based sampling methodology used to collect study data warrants comment because error could be introduced if any incorrect patient information was included. However, validation of actual procedure notes and lab test records supplied by a random audit of >10% of the total respondent group assuaged these concerns. Moreover, patient questionnaire-based data analyses may be affected by low response and recall bias. In this investigation the response rate approached 90%, an unusual feature we attribute to the participants being generally well educated and highly motivated, obtained from a closed-membership internet support group. Additionally, these data were collected from patients who self-selected into a voluntary support group, so it cannot be known if these respondents are representative of all unplanned pregnancies after HS. Importantly, estimating contraceptive failure rate based on these data is inappropriate (and outside the scope of our study) because it was impossible to determine with accuracy the geographical origins of study participants. Recall bias also cannot be excluded, but a planned follow-up study involving detailed, independent review of patient medical records will be helpful in this regard. Finally, we were unable to assess characteristics of the practitioners who performed HS in this dataset, so there could be specific physician factors associated with contraceptive performance with HS that escaped detection.

Considering the patient data presented here, previous risk models [12] based on a relatively high first-year failure rate (i.e., pregnancy occurring within the first year after HS) appear valid but may still require some recalibration. Our analysis of contraceptive failure with HS did identify a peak unplanned pregnancy incidence within the first 12 months of device placement, but mean interval to pregnancy after HS was closer to 20 months. We may thus speculate that even if these patients had availed of an alternate method of contraception in the first three months following HS, many unplanned pregnancies would have still occurred. Since contraceptive efficacy for HS is often reported based on total number of HS devices sold during a reference period rather than the actual number of patients who undergo HS (Fig. 2), the published failure rate for HS may not be reliable [9]. Calculating contraceptive efficacy using absolute patient count instead of product inventory data may give a more accurate impression of actual or "real-world" HS experience, as described previously [12]. Additional research is needed to complete our understanding of outcomes following HS.

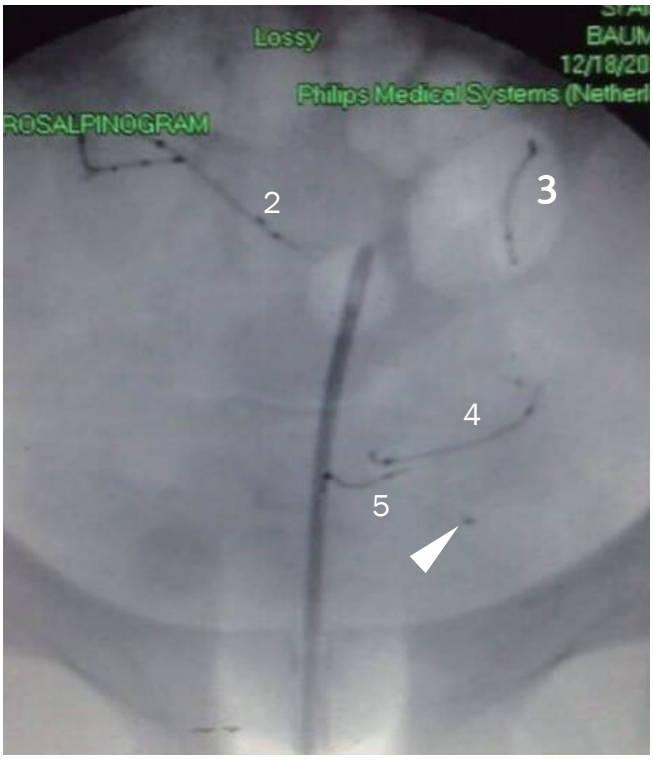


**Fig. 2.** Early (pre-contrast) hysterosalpingogram image performed three months after hysteroscopic sterilization. This radiograph illustrates placement of more than the recommended two Essure devices. Terminal markers are seen for five intact implants (1 to 5), and a fragment of a sixth device is also suggested (arrow).

## Conflict of interest

No potential conflict of interest relevant to this article was reported.

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