

HYSTEROSCOPIC STERILIZATION

What you need to know about HSG confirmation

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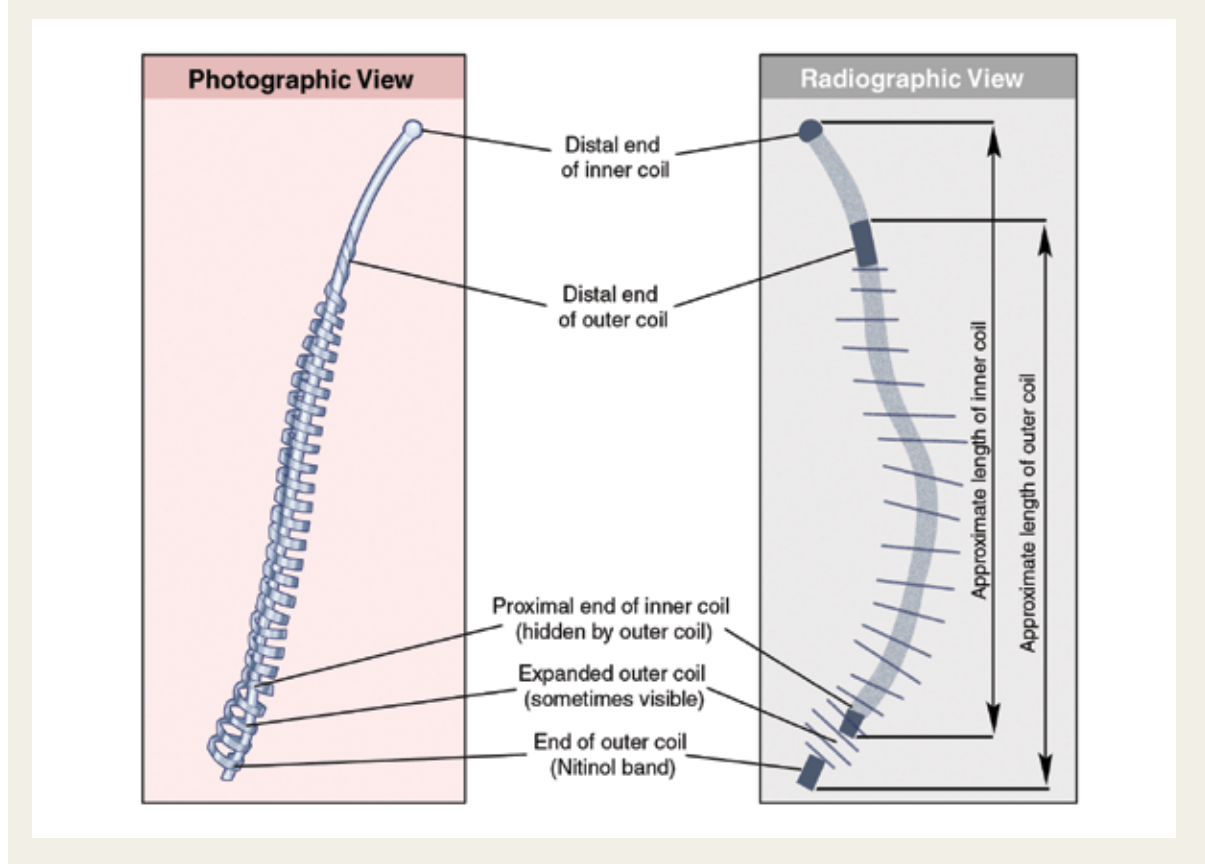
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Hysteroscopic sterilization represents a viable option for women who desire permanent sterilization. However, the need for a confirmatory hysterosalpingogram (HSG) may be perceived as a challenge for obstetrician/gynecologists (ObGyns) and their patients. Radiologists may be unfamiliar with the specifics of HSG as used to confirm tubal occlusion. Patients may not understand the importance of the HSG.

Such barriers are easily overcome. This monograph describes how a leading ObGyn and radiologist manage the collaborative process required for best outcomes in patients who are interested in the Essure hysteroscopic sterilization procedure.

HSG confirmation: Collaboration between ObGyn and radiologist

Dr Lipman: I often see a disconnect between the radiologist who performs the HSG and the referring ObGyn. The radiologist may not understand that the HSG required for confirmation of Essure placement differs significantly from an HSG to evaluate infertility. The confirmation test requires much less pressure and produces minimal discomfort compared with the traditional HSG, in which tubes are pressure-tested. The radiologist needs to be familiar with the Essure device,

FIGURE Correct placement of Essure micro-insert

including its pre- and postinsertion appearance as well as the radiographic markers on the micro-insert (FIGURE).

The Conceptus (manufacturer of Essure) HSG protocol recommends 6 radiographic views to confirm occlusion of each tube. The radiology report should contain specific information needed by the ObGyn, which I refer to as the 3 P's: confirmation of presence of the micro-inserts, description of the position of the inserts, and documentation that the tubes are plugged. In addition to providing a written report, I typically review the findings by telephone with the ObGyn. If I see a partial or incomplete occlusion, I will follow up with both the patient and the ObGyn for additional evaluation.

Dr Famuyide: You raise an important point about collaborative and integrated patient care. At our institution, we are fortunate to have a team of minimally

invasive gynecologic surgeons and radiologists who specialize in gynecologic procedures and who perform our HSGs. We have good results with this type of collaboration, both in terms of following through with a decision to have the hysteroscopic sterilization and in patient compliance with the HSG.

I consider placement of each micro-insert successful if less than 50% of the inner coil trails into the uterine cavity. Distal placement is correct if the device is located no further than 30 mm from the uterotubal junction.

We formally grade our HSGs according to criteria presented by Dr Wittmer and colleagues.¹ In that study, the HSGs of 32 patients were assessed as follows: Grade I represented cornual blockage. Grade II featured filling of the tubes, but the dye did not extend beyond any portion of the coil. Grade III showed that the dye went beyond the outer coil or spilled into the peritoneal cavity. Grades I and

It were satisfactory in terms of demonstrating tubal occlusion. Of the patients evaluated in this study, only 1 micro-insert showed improper positioning, although that fallopian tube was blocked.

Dr Lipman: We have had similar results: In our experience, tubes that are not fully occluded at 3 months generally show complete occlusion when evaluated at 6 months.

Dr Famuyide: Yes, our experience among our patient population has been similar. We have performed hysteroscopic sterilization procedures in 300 patients over the past 4 to 5 years. We have had 4 patients who had either unilateral or bilateral patent tubes at 3 months. At 6 months, all showed tubal occlusion. In 1 patient, HSG revealed bilateral tubal diverticular disease, making it difficult for the Essure device to contact the intima or the mucosa of the fallopian tube. Even in that patient, bilateral occlusion occurred within 6 months.

Managing patient perceptions: Procedure ends with HSG

Dr Famuyide: A recent report showed that only 12.7% of patients returned for follow-up HSG.² In our practice, follow-up rates are much higher. We describe the procedure so that the patient fully understands that HSG confirmation is part of the process; I think this contributes to our success. Our patients also are told they need to rely on an alternate form of contraception during the 3 months between the device placement and HSG confirmation.

Dr Lipman: I don't think that HSG is a significant hurdle for my patients. Of course, a certain amount of self-selection occurs before a patient contacts my office directly—she has already determined that she wants the least invasive sterilization procedure available. Typically, she has been counseled by her ObGyn and understands the difference between hysteroscopic and laparoscopic sterilization. This patient is very similar to someone interested in uterine fibroid embolization: She wants a nonsurgical approach. I should note that I was one of the investigators in the

original Essure trial, which included placement under both hysteroscopic and fluoroscopic guidance (currently an off-label use of the device). So I have considerable experience with placing the devices, as well as in confirming their placement by HSG.

Dr Famuyide: We also have found that patients accept the benefit (and importance) of the HSG. We recently published data describing a cohort of 191 patients who had micro-insert placement.³ One arm enrolled patients with cardiac disease who were not candidates for laparoscopic sterilization (26 patients); the other arm was the control group. Of all study participants, 95% had successful device placement under conscious sedation. Among the cardiac patients, successful placement was achieved in all patients. In the control group, 1 patient had prior salpingectomy and needed only unilateral placement. An additional 8 patients had placement failure: in 5 women, this was a result of anatomic abnormality; in 3 women, failure was due to tubal spasm. Of the women with placement failure, 6 had laparoscopic sterilization at the time of the attempted hysteroscopic placement; 2 had interval laparoscopic sterilization.

It should be noted that the cardiac patients were highly motivated and aware that any future pregnancy could be fatal: 100% of the patients had a follow-up HSG according to schedule. However, even among the general population, we had a 90% follow-up rate.

Dr Lipman: In terms of hysteroscopic sterilization, it is incumbent upon the performing physician to emphasize that the procedure is not finished until the Essure confirmation test is done.

Deciding on sterilization: Patient counseling

Dr Famuyide: The decision to have permanent sterilization is difficult. Patients are slightly more likely to cancel appointments for an initial consultation about permanent sterilization than an appointment to discuss a clear gynecologic problem, such

as menorrhagia. This is understandable, particularly in the case of a younger woman who may not be entirely certain that permanent sterilization is the best option at this point in her life.

Prior to scheduling a sterilization procedure, we carefully review the pros and cons of all non-permanent contraceptive methods with the patient. Oral contraceptives may be a good option for a patient with a history of menorrhagia or irregular cycles. Intrauterine devices offer long-term contraception, as well as cycle control, and can be appropriate for many patients.

If the patient is interested in permanent contraception, I review the hysteroscopic and laparoscopic options. I counsel the patient that both procedures are permanent and irreversible.

I tell patients that laparoscopic procedures are effective immediately and do not require additional birth control. However, the procedure is invasive and the patient will need to be monitored in the hospital for a few hours.³ Complication rates from laparoscopic procedures are approximately 1 in 1000. Recovery averages 5 to 7 days. Activities are limited for another week to 10 days, with restrictions on lifting objects that weigh more than 15 lb. This may be problematic for women who have young children or work in settings that require physical activity. However, laparoscopic sterilization may be the most appropriate option for a patient with a concomitant problem, such as pelvic pain. For these patients, the surgery provides an opportunity to evaluate the cause of the problem.

Hysteroscopic sterilization offers benefits that may appeal to many patients: it is nonincisional; it can be performed in the office with or without sedation; and recovery is rapid, with no restrictions on activities. The one requirement is that the patient must return in 3 months for the HSG to ensure that the tubes are completely blocked. Until that confirmation is provided, the patient will need to continue with an effective form of contraception. The procedure is contraindicated for a woman who has an allergy to nickel, as confirmed by a skin test.

Using Essure in conjunction with endometrial ablation

Dr Lipman: There are special considerations for the woman who is interested in having both hysteroscopic sterilization and endometrial ablation. For this patient, the HSG may be quite painful because of the scarring of the uterine cavity.

Dr Famuyide: That is an important point, and it underscores the need for close collaboration between the ObGyn and the radiologist. We published a paper in the *Journal of Minimally Invasive Gynecology* last year in which we reported on 25 patients who had a combined procedure.⁴ They did not rate the procedure as being painful. At 3 months, ablation was not a factor in interpreting the HSG. Since then, we've performed combined procedures on 50 patients, and we continue to do so. There is an important caveat, however: If more than 3 months elapse, the HSG becomes increasingly difficult, both in terms of pain and in interpreting the results. We documented that in our paper.⁴ Clearly, the development of sequelae after endometrial ablation is a time-dependent process. Several of our patients did not return for the HSG until 9 months had passed. As you've described, the HSG was extremely uncomfortable and the time lapse made it difficult for us to get a good interpretation from the dye study. ■

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