Interstitial Ectopic Pregnancy in a 34-Year-Old Woman After Removal of Essure Microinserts and Reversal of Hysteroscopic Sterilization

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Patient: Female, 34-year-old
Final Diagnosis: Ectopic pregnancy
Symptoms: Pain
Medication: —
Clinical Procedure: —
Specialty: Obstetrics and Gynecology

Objective: Unusual clinical course
Background: Interstitial ectopic pregnancy, a pregnancy occurring in the part of the fallopian tube that is within the body of the uterus, poses a significant risk to patients, with a mortality rate of up to 2.5%, which is 7 times higher than for tubal ectopic pregnancies. Hysteroscopic sterilization reversal carries a potential risk of interstitial ectopic pregnancy; therefore, it is important to counsel patients appropriate and review the alternative option for in vitro fertilization. In vitro fertilization has been shown to have a superior pregnancy and live birth rate in comparison to sterilization reversal. Women who have undergone sterilization via hysteroscopic placement of the Essure device may complete in vitro fertilization with sterilization devices left in situ without significantly reducing the pregnancy rate.

Case Report: A 34-year-old woman, G6P3023, presented to the Emergency Department after incidental detection of left interstitial ectopic pregnancy measuring 9 weeks of gestation. She had previously undergone a right salpingectomy for ectopic pregnancy soon after reversal of Essure sterilization via bilateral tubouterine reimplantation; this is a procedure that is infrequently performed due to limited evidence to suggest that this is a safe and efficacious method to achieve future pregnancies. This patient underwent an uncomplicated left cornuostomy and salpingectomy, rendering the need for in vitro fertilization to conceive in the future.

Conclusions: Patients seeking fertility treatment after hysteroscopic sterilization should be counseled that tubouterine reimplantation poses significant morbidity risk based on the nature of the surgery. Instead, patients who have undergone hysteroscopic sterilization who desire future pregnancy should be advised that in vitro fertilization, with or without salpingectomy, may be a safer and more efficacious option to achieve live birth.

Keywords: Fertilization in Vitro • Pregnancy, Ectopic • Sterilization Reversal

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Background

Sterilization is the second most common form of contraception for women in the United States [1]. Despite its permanent nature, up to 20% of women who have undergone sterilization procedures seek reversal [1]. One form of sterilization, the Essure microinserts, involves the placement of nickel-titanium coils into the tubal ostia, creating scar tissue and effectively occluding the fallopian tubes [2]. Although Bayer stopped manufacturing Essure microinserts for hysteroscopic sterilization on 31 December 2018, more than 750,000 women have had the device placed since its approval by the United States Food and Drug Administration (FDA) in 2002 [2,3]. With the increasing reports of adverse effects potentially related to Essure microinserts, removal of these devices has become an increasingly common surgical procedure among gynecologists. For women who not only want the Essure removed, but also want to restore fertility, Essure reversal can be an attractive option for this vulnerable population.

Cumulative live birth rate in women with tubal factor infertility who undergo in vitro fertilization (IVF) may be as high as 55.8%, but many women still seek surgical reversal [4]. The delivery rate after tubal ligation reversal has been reported to range from 25% to 82%, depending on the age of the woman and preoperative length of the fallopian tubes; however, the hysteroscopic sterilization reversal surgical technique is distinct from typical tubal reanastomosis [5].

In hysteroscopic sterilization reversal, tubal reanastomosis is performed at the interstitial-ampulla portion of the fallopian tube, and yields a significantly higher ectopic pregnancy rate (20.0%) compared with other anastomosis sites (0.3-2.2%) [6]. Moon et al retrospectively analyzed 961 patients who underwent tubal reversal (via reanastomosis of various parts of the fallopian tube, no more proximal than the isthmic region) and found an overall ectopic pregnancy rate of 2.5% [6]. The pregnancy rate in the study was 87.9%, with the best outcomes among those having isthmus-to-isthmus reanastomosis [6]. The American Society for Reproductive Medicine (ASRM) supports tubal reanastomosis, but has clearly stated that this recommendation does not apply to correction of proximal tubal occlusion due to low success rates and risk of cornual rupture in cases of pregnancy [7].

A pregnancy in the tubal segment traversing the muscular wall of the uterus, also known as an interstitial ectopic pregnancy, occurs in 2-4% of all tubal pregnancies [8]. These pregnancies are exceedingly dangerous, with mortality rate up to 2.5% (7 times greater than ectopic pregnancies in the tubal ampulla or fimbria). This high mortality is likely due to the fact that patients may remain asymptomatic until 7 to 16 weeks of gestation [8]. With pregnancies reaching a more advanced gestational age, minimally invasive surgical routes are often not feasible, posing higher risk of morbidity to the patient by requiring laparotomy for surgical resection. Although cornuostomy or salpingotomy is preferred for uterine preservation, cornual excision or wedge resection is recommended for pregnancies measuring greater than 4 cm in size [8]. Ultrasound has significantly improved detection and survival, with 88-93% specificity if the following characteristics are present: empty uterine cavity, chorionic sac separated at least 1 cm from the lateral edge of the uterine cavity, and a thin myometrial layer surrounding the gestational sac (less than 5 mm) [8].

While the risk of ectopic pregnancy following traditional tubal reanastomosis reportedly ranges from 2% to 10%, sterilization reversal with tubouterine reimplantation has been reported to be achieved in approximately 5% in a small case series [9]. Uterine rupture is rarely described in pregnancies achieved following traditional tubal reanastomosis, and it is reported to be less than 4% with tubouterine reimplantation [9,10].

Hysteroscopic sterilization reversal not only poses a significant risk to the patient, but has a relatively low live birth rate, with 1 case series citing a 27% live birth rate following sterilization reversal [10]. Undergoing IVF with Essure microinserts in place may be superior to this, as investigators have demonstrated a 75% pregnancy rate with 66.6% live birth rate among patients with hydrosalpinges [11].

Case Report

A 34-year-old woman, G6P3023, presented to the Emergency Department after an early first-trimester ultrasound incidentally detected a left interstitial ectopic pregnancy. The patient had undergone sterilization reversal, with removal of bilateral Essure devices, 2 years prior to this presentation. The sterilization reversal was completed at an outside institution via laparotomy with bilateral tubouterine reimplantation.

After trying to conceive for nearly 1 year following tubouterine reimplantation, the patient had a right tubal ectopic pregnancy requiring laparoscopic right salpingectomy. Chromopertubation at that time demonstrated left fallopian tube patency. She continued to try to conceive for 9 months, including 3 cycles of clomiphene citrate ovulation induction, without conception; therefore, hysterosalpingogram was completed and again demonstrated left tubal patency (Figure 1). Eight months after this imaging, the patient established care with Reproductive Endocrinology and Infertility for possible IVF, but spontaneously conceived prior to initiating treatment.

After arriving to the Emergency Department, additional ultrasound imaging demonstrated a gestational sac with a fetus...
**Figure 1.** Hysterosalpingogram prior to pregnancy.
Hysterosalpingogram image showing a filling defect at the site of prior right salpingectomy, and left tubal patency.

**Figure 2.** Ultrasound of interstitial ectopic pregnancy measuring 9 weeks. Ultrasound imaging depicting a 9-week gestation within the left lateral myometrium of the uterus.

**Figure 3.** Ultrasound of pregnancy without intrauterine implantation. Ultrasound imaging demonstrates a gestational sac within the tubal interstitium, and the endometrial lining of the cavity is non-contiguous, with decidual reaction surrounding the pregnancy.

**Figure 4.** Pregnancy nearly ruptured through uterine serosa. Interstitial pregnancy protruding from the left posterior aspect of the tubal insertion site into the uterus. Babcocks denote the left fallopian tube.

**Figure 5.** Pregnancy delivered through uterine serosa. The pregnancy was superficial to the overlying serosa and gestational sac, with embryonic contents delivered en caul following serosal incision.
in the left lateral myometrium, separate from the endometrial canal, consistent with an interstitial ectopic pregnancy measuring 9 weeks and zero days, with cardiac activity present (Figures 2, 3). Serosa was noted to be nearly 2 mm in thickness overlying the pregnancy. The patient was counseled on treatment options and ultimately underwent an uncomplicated resection of left interstitial pregnancy via laparotomy, with elective left salpingectomy. The procedure was notable for superficial interstitial pregnancy protruding from the left posterior aspect of the tubal insertion site and subsequent en caul delivery of pregnancy products following the serosal incision (Figures 4, 5). The uterine defect was closed in multiple layers, similar to traditional uterine reaproximation following a myomectomy. The patient had an uncomplicated postoperative course and plans to pursue IVF in the future.

**Discussion**

Although the cost of IVF can vary greatly by geographic location and medical insurance coverage plan, the American Society for Reproductive Medicine estimates the average cost of one fresh IVF cycle to be $12 400 [12]. For women 40 years of age or younger who desire pregnancy after a clip or ring tubal ligation, tubal reanastomosis may be more cost-effective than IVF when the cost of IVF is over $4500 [13]. However, this is not applicable to women who have had hysteroscopic sterilization, as the most proximal portion of the fallopian tube, rather than the ampulla, is compromised, requiring tubouterine reimplantation instead of simple reanastomosis. The reported surgical technique for microinsert removal includes making transverse posterior-fundal uterine incisions to allow for tubouterine reimplantation, bypassing the scarred fallopian tube [10]. This posterior-fundal part of the tubal isthmus is exactly where the tubal pregnancy was found to have nearly ruptured from beneath the uterine serosa in our patient’s case (Figure 4).

Given the potential risk for interstitial ectopic pregnancy in women who undergo tubouterine reimplantation, it may be preferred to investigate options for IVF, either with microinserts left in situ or following bilateral salpingectomies. There is good evidence to suggest that pregnancy can be achieved with Essure microinserts in place [11]. In fact, in a prospective cohort study by Cohen et al, Essure actually improved IVF pregnancy and live birth rates in women with hydrosalpinges [11]. Because the rate of interstitial ectopic rate is very low and most evidence is based on case reports and series, it is challenging to directly compare the interstitial ectopic rate following hysteroscopic sterilization with surgical reversal versus IVF with microinserts left in place. Although reports of interstitial pregnancy following IVF have been noted, these patients have not specifically undergone Essure sterilization reversal [14]. When comparing IVF outcomes following hysteroscopic sterilization or laparoscopic tubal occlusion for bilateral hydrosalpinges, no ectopic pregnancies were noted in the patients who had hysteroscopic tubal occlusion [15]. While it cannot be assumed that the rate of interstitial pregnancy from IVF after hysteroscopic sterilization is negligible, the currently available evidence suggests that this rate is very low. Furthermore, the existing literature, including this case report, repeatedly demonstrates the risk of interstitial pregnancy following sterilization reversal involving the interstitial-ampulla portion of the fallopian tube, while the safety and efficacy of IVF with Essure microinserts in place has been well-established [6,16]. Therefore, it is anticipated that the rate of interstitial ectopic pregnancy following IVF with Essure in place would be lower than the rate following Essure reversal with tubouterine reimplantation.

Whether a woman who has undergone hysteroscopic sterilization proceeds with IVF with microinserts in place or after salpingectomies, she should have close follow-up ultrasound imaging in early pregnancy for early detection of reimplantation outside of the uterus.

**Conclusions**

Given the recent removal of Essure from the market, there is a large population of women who are not only interested in regaining their fertility, but also having the implants removed due to potential or current adverse effects. Hysteroscopic sterilization reversal is becoming a more common surgical technique despite a lack of long-term data on future pregnancy outcomes. Women who are considering reversal need to be extensively counseled on the variable and even unknown rate of highly morbid interstitial ectopic pregnancy. The benefits and risks of IVF should be thoroughly discussed with these patients, including the option to remove or retain Essure devices, as both are safe and effective options prior to proceeding with IVF.

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**Declaration of Figures’ Authenticity**

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.
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