Novel treatment (new drug/intervention; established drug/procedure in new situation)

Successful placement of the Essure device after a failed procedure using the Adiana system for hysteroscopic sterilisation

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Summary

This case report describes a successful hysteroscopic sterilisation using the Essure Permanent Birth Control device (Conceptus Inc., Mountain View, California, United States) after a failed procedure of the Adiana Permanent Contraception system (Hologic, Inc., Bedford, Maryland, United States). The delivery catheter of the Adiana system was able to be inserted into the left fallopian tube without difficulty and per manufacturer specifications. However, the position detection array was unable to sense four-quadrant tissue contact. The same issue occurred at the contralateral tube. Using the Essure system, the coils were able to be placed in both ostia easily and adequately. In patients in whom the Adiana system fails to occlude the fallopian tubes due to procedural, anatomic or device-related factors, the Essure procedure may be an efficient alternative.

BACKGROUND

Over the years, permanent contraception in women has become a common form of birth control. Several techniques to obtain tubal occlusion are available. Hysteroscopic sterilisation is known as an effective method of permanent contraception with several advantages over more invasive approaches.

The first transcervical procedure approved by the US Food and Drug Administration (FDA) is the Essure Permanent Birth Control device (Conceptus Inc., Mountain View, California, United States) in 2002.¹ Using the Essure system, a micro-insert is deployed in the proximal portion of each fallopian tube. The insert consists of an inner coil of stainless steel and polyethylene terephthalate (PET) fibers, and an outer coil of nickel titanium. The outer coil expands upon release to anchor the micro-insert in the varied diameters and shapes of the fallopian tube. The device's effectiveness as a contraceptive is believed to be due to a combination of its space filling design and a local tissue response to the PET fibers resulting in tissue in-growth into the micro-insert. Both mechanisms elicit an occlusion of the fallopian tubes and thereby initiate permanent contraception.¹

The second form of hysteroscopic sterilisation, the Adiana Permanent Contraception system (Hologic, Inc., Bedford, Maryland, United States), received approval from the FDA in 2009.² This system combines superficial thermal injury of the fallopian tube and placement of a silicone matrix into the lumen. A delivery catheter is inserted into the tubal ostium, where it confirms full tissue contact via the position detection array (PDA) in order to assure correct positioning. The PDA is composed of four sensors located circumferentially in four quadrants around the catheter. In correct position, the sensors detect uniform tissue contact, which is communicated to a radiofrequency generator. The Adiana device then creates a superficial lesion within

the fallopian tube by delivering bipolar radiofrequency energy through the catheter. Following this ablation, a silicone matrix is deployed, which functions as a permanent scaffold during wound healing. The tissue in-growth response initiated by the lesion will lead to integration of fibrous tissue into the matrix, which results in occlusion of the tube.²

Approximately 10 000 women undergo a tubal occlusion procedure in the Netherlands each year, of whom one third chooses a hysteroscopic approach. The Essure Permanent Birth Control method has been the most applied form of hysteroscopic sterilisation in the Netherlands since its introduction in 2003. The Adiana Permanent Contraception system has been used since its Conformité Européenne marking approval in 2009.

Gimpelson *et al.*³ reported a case in which bilateral placement of the Essure device failed, whereas the Adiana procedure could be successfully completed. They concluded that in patients in whom tubal structural abnormality prevents adequate depth for Essure insertion, Adiana might be an effective alternative due to its shorter required placement length.

The present case report describes a successful completion of sterilisation using the Essure system after a failed placement of the Adiana device.

CASE PRESENTATION

A 48-year-old woman underwent a hysteroscopic sterilisation using the Adiana system. The procedure was performed in an ambulatory surgery setting. During hysteroscopic inspection, a normal uterine cavity with both tubal ostia and bilateral pseudo ostia were visualised. An uncomplicated and correct positioning of the catheter into the intramural section of the left fallopian tube was achieved. However, the PDA did not confirm full tissue contact, and therefore the radiofrequency generator could

Figure 1 X-ray of Essure devices.

not be activated. At the contralateral side the same issue occurred. The Adiana procedure was terminated after several attempts.

Conversion to the Essure Permanent Birth Control system was performed to initiate tubal occlusion in the same session. The Essure delivery system was inserted through the working channel of the hysteroscope. The delivery catheter was advanced into the left fallopian tube without difficulty until the black positioning marker reached the ostium. After retraction of the catheter away from the micro-insert, approximately 1 cm of the wound down coil was exposed into the uterine cavity. The delivery wire was then detached from the micro-insert and the outer coils expanded to conform to the fallopian tube. The procedure was repeated at the contralateral tube. Once the delivery system was removed, three expanded outer coils were visible in both tubal ostia.

After 3 months, radiographic and ultrasound visualisation of the implants was performed (figure 1). These observations showed a satisfactory bilateral cornual location of the micro-inserts and a proper configuration. The patient was instructed to cease her alternative contraception.

DISCUSSION

Hysteroscopic sterilisation has proven to be an efficient and safe method of permanent contraception. Its minimal invasive approach offers lower complication rates, less patient discomfort and shorter recovery time compared to its laparoscopic alternative. Moreover, it is often preferred

due to the minimal anaesthesia required, which allows the procedure to be performed outside the operation room.

In the Netherlands, hysteroscopic sterilisation using the Essure system is still the method of choice, considering the amount of experience gained over the years. Two clinical trials demonstrated the safety and effectiveness of the Essure system in providing permanent contraception.¹ A successful procedure with bilateral device placement was achieved in 89% after one or two attempts. Although, recent studies with new generation models show higher placement rates (94.6–99%).⁴ The most common reasons for placement failure are tubal obstruction and visualisation problems due to uterine anatomy. Of the women with bilateral micro-insert placement, 97% were ultimately able to rely on the Essure system for contraception. Inability to rely on the Essure procedure after achieving bilateral placement was due to misplacement of the micro-inserts which resulted in expulsion, perforation or other unsatisfactory micro-insert location. Based on 4 years of follow-up, an effectiveness rate of 99.8% was established in preventing pregnancy.^{1 5}

The EASE trial (evaluation of the adiana system for sterilisation using electrothermal energy) was conducted to evaluate the safety and effectiveness of the Adiana Permanent Contraception device.² The adverse event outcomes of the EASE study indicate that the device is reasonably safe. Ectopic pregnancies did occur during the clinical trial. However, the rate of occurrence was reported as similar to or less than that reported for other sterilisation

methods. A successful bilateral placement of the matrices was achieved in 94% of the patients after the first procedure. The overall success rate was 95%, as some patients underwent a successful second attempt. Failure of bilateral placement was mostly due to tubal access failures that occurred because of patient anatomy issues. Suspected tubal blockages, extremely lateral tube location, uterine adhesions, poor visualisation of the ostia and other varied tubal abnormalities were reported. After an additional hysterosalpingography, 88% of the women treated were able to rely on the Adiana device for contraception. The pregnancy prevention rates were comparable to other methods of tubal occlusion. A 3-year pregnancy prevention effectiveness rate of 98.4% was established in the clinical trial.^{2 6}

In the present case, the Adiana procedure was terminated because the four sensors of the PDA could not detect tissue contact simultaneously. The mechanisms responsible for this failure could be classified as procedural, anatomic, or device-related. During hysteroscopic procedure, a non-ionic distention medium (e.g., 1.5% glycine, 3% sorbitol, 5% mannitol) is used. The inflow might increase the diameter within the fallopian tube, preventing full tissue contact with the PDA. Tubal anomalies or normal variants of tubal anatomy might also disrupt detection via the PDA. Device-related failure could be due to a deficient catheter performance.

Both the Adiana and the Essure transcervical sterilisation methods have proven to be well tolerated, safe and effective. Bilateral placement rates, adverse events and rates of tubal occlusion are comparable. In some patients, Adiana may be preferred since the shorter length of the device allows insertion in case of tubal abnormalities. Conversely, the Essure device may be an efficient alternative if the PDA of the Adiana catheter fails to monitor full tissue contact, as seen in the present case. Further research may be necessary to clarify whether one device is superior to the other. Each system appears to be favourable in specific situations and adjustment to individual cases is necessary in order to facilitate adequate sterilisation.

Learning points

- ▶ Both the Adiana and the Essure transcervical sterilisation methods have proven to be well tolerated, safe and effective.
- ▶ In patients in whom the Adiana system fails to occlude the fallopian tubes due to procedural, anatomic or device-related factors, the Essure procedure may be an efficient alternative.
- ▶ Further research may be necessary to clarify whether one device is superior to the other. Each system appears to be favourable in specific situations and adjustment to individual cases is necessary in order to facilitate adequate sterilisation.

Competing interests None.

Patient consent Obtained.

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