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Author

Hou, Melody Y

Publication Date

2016-07-01

DOI

10.1136/bcr-2016-216535

Peer reviewed

CASE REPORT

Discordant relationship between Essure microinsert position and tubal occlusion

Melody Y Hou

Department of Obstetrics and Gynecology, University of California, Davis School of Medicine, Sacramento, California, USA

Correspondence to
Dr Melody Y Hou,
myhou@ucdavis.edu

Accepted 11 July 2016

SUMMARY

Hysteroscopic sterilisation with Essure requires confirmation of tubal occlusion by hysterosalpingogram or microinsert position by transvaginal sonography 3 months after placement before women can rely on the method for pregnancy prevention. A 39-year-old woman underwent hysteroscopic sterilisation via Essure, with successful bilateral tubal occlusion documented on hysterosalpingogram. She had a subsequent unintended pregnancy and termination, and presented with persistent pelvic pain and other non-specific symptoms. She underwent a laparoscopic-assisted vaginal hysterectomy with bilateral salpingectomy, with complete resolution of her symptoms. Pathological evaluation demonstrated a perforated Essure microinsert and ipsilateral tubal occlusion, and a correctly placed Essure microinsert with ipsilateral tubal patency. Clinicians should be cautious about the assumption that correctly placed microinserts based on ultrasonography, hysterosalpingogram or laparoscopic evaluation assures occlusion success.

BACKGROUND

Female sterilisation is a popular method of contraception worldwide.[1] Methods for female sterilisation include salpingectomy, tubal ligation, laparoscopic tubal occlusion and hysteroscopic tubal occlusion.[2] The last, marketed as Essure (Bayer HealthCare Pharmaceuticals, Whippany New Jersey, USA), involves inserting nickel/titanium alloy coils containing polyethylene fibres into the fallopian tubes, which cause a fibrotic reaction to occlude the tubes and prevent fertilisation.[3] The procedure's advantages include no incisions or need for general anaesthesia.[4] Since its introduction in 2002 in the USA and up to 2013, more than 750 000 procedures have been performed worldwide.[5] In the USA, the Food and Drug Administration (FDA) mandates a confirmation test via hysterosalpingogram (HSG) to confirm tubal occlusion, and recently included ultrasound evaluation of coil location to confirm correct placement as another acceptable assessment in July 2015.[6] This case report describes a woman presenting with persistent pelvic pain after a pregnancy termination following Essure placement. This case demonstrates that successful occlusion can be unpredictable and discordant with the position of the microinserts in the same patient as assessed by ultrasound, HSG and gross examination by laparoscopy.

CASE PRESENTATION

A 39-year-old gravida 5, para 3 woman presented to our clinic reporting diffuse pelvic pain, left greater than right, after hysteroscopic sterilisation via Essure microinsert placement performed 6 years previously. She had an HSG 3 months after the procedure which demonstrated occlusion. One year after the sterilisation procedure, she became pregnant. She chose to terminate the pregnancy and her partner had a vasectomy after the abortion. Three years later, she began having back and pelvic pain, heavy menses and dysmenorrhoea. She also reported other non-specific symptoms, including hives, itchy hands and feet, hot flushes and night sweats.

INVESTIGATIONS

At her visit, a pelvic examination demonstrated fundal and cornual uterine tenderness, left greater than right. Transvaginal ultrasonography demonstrated a normal uterus with the left insert in or through the myometrium and the right insert in the appropriate position (figure 1).

TREATMENT

The patient underwent an uncomplicated laparoscopic-assisted vaginal hysterectomy with bilateral salpingectomy, and was discharged home the same day.

OUTCOME AND FOLLOW-UP

On gross examination, the distal end of the left microinsert was embedded in the myometrium under the serosa near the left tube, but not entering the isthmus of the fallopian tube. The right microinsert was appropriately positioned within the right fallopian tube, transversing the myometrium to enter the isthmic portion of the tube (figure 2). On

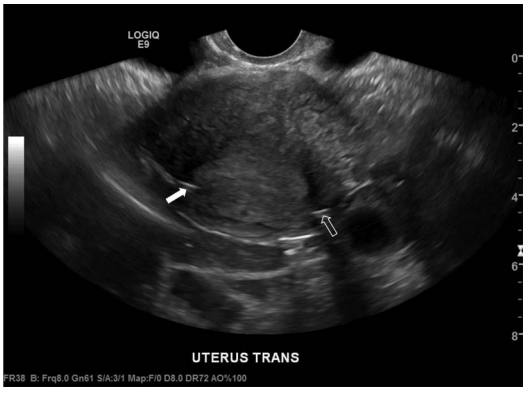

Figure 1 Transvaginal ultrasound revealing an appropriately positioned Essure microinsert (solid arrow) within the right fallopian tube; the microinsert on the left (open arrow) appearing to be in or through the myometrium.

To cite: Hou MY. *BMJ Case Rep* Published online: [*please include* Day Month Year] doi:10.1136/bcr-2016-216535

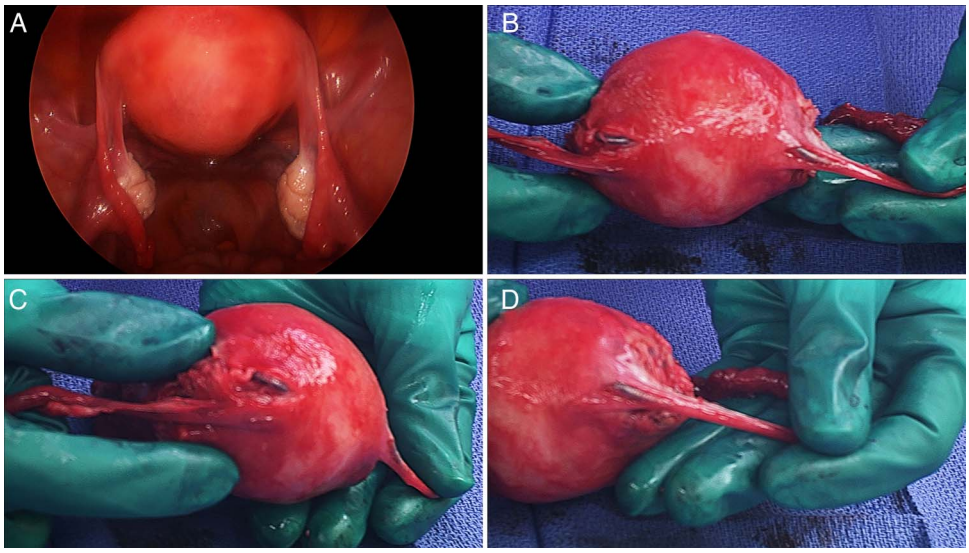

Figure 2 Intraoperative laparoscopy view of the uterus, tubes and ovaries (A); gross uterine specimen in the intraoperative orientation (patient left on picture left) with both cornua opened, revealing (B); an Essure microinsert perforating the myometrium anterior to the left fallopian tube (C); and a microinsert within the lumen of the right fallopian tube (D).

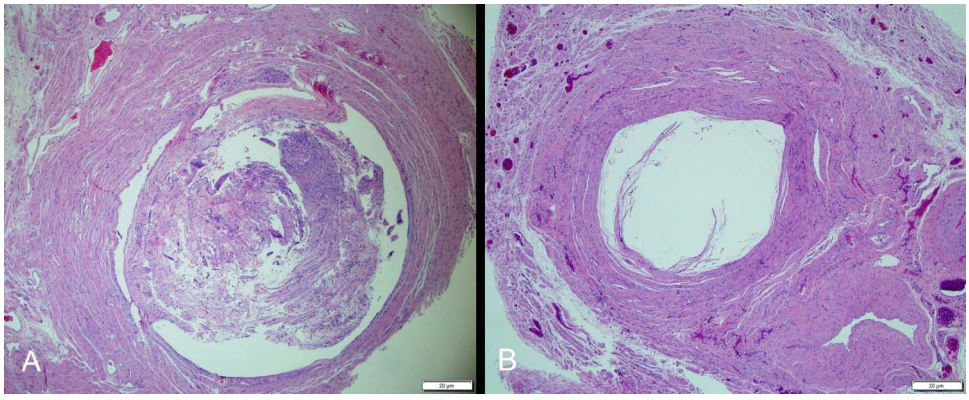

Figure 3 Microscopic evaluation by H&E stain of fallopian tubes demonstrating a fibrosis-filled lumen of the left fallopian tube and (A) a patent right fallopian tube (B).

microscopic examination, the right fallopian tube lumen was not obliterated, whereas the left fallopian tube lumen was obliterated and showed fibrosis (figure 3). The patient returned for her postoperative visit 6 weeks later and reported that both her gynaecological and non-specific symptoms had completely resolved.

DISCUSSION

More than 10 million American women rely on female sterilisation to prevent pregnancy.[1 4] Since the introduction of Essure hysteroscopic sterilisation in 2001, increasing numbers of women are undergoing this route of sterilisation, but concerns regarding effectiveness and complication rates have been raised.[2 5] The FDA mandates a confirmation test, either an HSG to confirm tubal occlusion or very recently transvaginal ultrasonography, to confirm correct microinsert placement.[3] Case reports of pregnancy following hysteroscopic sterilisation generally occurred among women who did not have imaging follow-up or had inadequate confirmation of placement or occlusion, but some pregnancies have occurred among women with documented occlusion or correct microinsert position.[6]

Patient's perspective

- When I was first implanted with Essure, I thought it was a great permanent birth control. However, later I would discover otherwise. A year after being implanted, I became pregnant. I cannot describe how devastated and betrayed I felt. Why did this product fail me and, more importantly, why did not the manufacturer want to learn why it failed? I felt abandoned.
- Over the following years, my symptoms and pain increased. I suffered fatigue, hair loss, swelling of my hands and feet, chronic itchy skin, anxiety, depression, horrific back pain and brain fog. Following my hysterectomy, I was amazed at how much better I felt immediately after surgery. Learning that a coil had migrated was not surprising, due to the pain I experienced. However, learning that the side that the coil had migrated was completed blocked with scar tissue, but where the coil was in place and intact was NOT blocked was shocking. Since the removal of the device more than a year ago, nearly all of my symptoms, including severe bloating, have resolved and my family noticed an immediate difference.

This case report describes a woman who had an unintended pregnancy following hysteroscopic sterilisation that had been deemed successful based on HSG. When she presented later with pelvic pain, she was found to have a microinsert that had perforated the fallopian tube that was nevertheless occluded, and a correctly positioned contralateral microinsert that failed to cause tubal occlusion on that side. Pre-existing fibrosis of the tube may have prevented the correct placement of the microinsert into the tubal lumen. However, the discordance between the microinsert positions and successful occlusion is striking. In some case reports of women who became pregnant following Essure, who were found to have perforated microinserts on laparoscopy, surgeons placed Filshie clips on the affected tube, with the assumption that the incorrectly placed microinsert was the cause of the occlusion failure.[7–9] This case demonstrates that correct positioning by ultrasonography, contained contrast by HSG, and even gross inspection by laparoscopy may not distinguish a successfully occluded tube from a failed patent one.

Learning points

- The same patient may have discordance between microinsert positioning and tubal occlusion success.
- Clinicians should not assume that a correctly placed microinsert on transvaginal sonography, demonstrated tubal occlusion on hysterosalpingogram, and a palpable microinsert within the fallopian tube on laparoscopy assure successful tubal occlusion.

Competing interests None declared.

Patient consent Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

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