Case Report

Current Opinion in Gynecology and Obstetrics Bilateral Essure Perforation into the Abdominal Cavity

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Abstract

The Essure implant is a Food and Drug Administration (FDA) - approved form of hysteroscopic sterilization. The device has been available since 2002 with over half a million placed in the United States. The safety and efficacy profile has been demonstrated in the literature and supported by the FDA. Here, we present a rare case of bilateral perforation into the abdominal cavity with one device ultimately left in-situ. Although Bayer, the manufacturer of Essure, plans to stop sale of the product by December 31, 2018 for financial reasons, providers may continue to have questions and concerns from implants placed previously.

Case Report

A 30-year-old woman, Gravida 2 Para 2, presented to our clinic for Essure hysteroscopic sterilization. Her medical history was significant only for obesity. She had no prior surgical history. Her procedure was uncomplicated with appropriate trailing coil tails seen post-procedure. She did not show up for her 3-month hysterosalpingogram (HSG) placement confirmation. Six months after placement, she returned for confirmatory imaging. At presentation, she had no complaints of pain or any gastroenterological complaints. HSG showed bilateral patency and could not confirm the devices were within her tubes. She underwent an abdominal x-ray, which suggested that at least one of the implants was within the peritoneal cavity. Hence, she was recommended to undergo a diagnostic laparoscopy. She also consented for bilateral salpingectomy.

For her procedure, a 10 mm umbilical incision was made with two accessory 5 mm bilateral lower quadrant port sites. The right Essure implant was laying in the right adnexa with mild adhesions (Figure 1) and easily removed. The intended left implant was wrapped around a section of small bowel (Figure 2). An intra-operative consultation was made with colorectal service for further recommendation. The colorectal surgeon ran the bowel

and decided against removing the implant. It did not appear to be embedded or constricting the lumen. Her salpingectomy was completed without any complications. She was discharged home on the same day of surgery.

Figure 1: Mild adhesions of implant to right adnexa.

Discussion

Tubal perforation and/or migration are rare adverse events after Essure placement. The reported incidence of perforation has been between 0.9 - 2.6% [1-3], although these numbers may be underreported especially if

patients are asymptomatic or lost to follow-up [4].

Figure 2: Essure implant around small bowel.

Most cases in the literature involve unilateral migration. In all these reports, the patients reported abdominal pain [5,6] and some manifested as small bowel obstruction requiring bowel resection [6]. In the case above, the dislocated implants obviously caused inflammation and formation of adhesive disease. Interestingly though, she denied any gastrointestinal symptoms. This just further highlights the importance of post-placement HSG assessment.

At laparoscopy, the left device, although stretched, did not have bowel muscular wall or lumen involvement. The thought was that if there was no bowel compromise six months post-procedure, it was better left in-situ as opposed to risking injury whilst trying to pry the clearly adhered implant off the bowel serosa.

Reports have identified procedural difficulty has a risk factor for Essure perforation [2,5]. However, review of placement operative note showed device was placed without incidence or complication. We contend the possibility of aberrant tubular anatomy that would contribute to bilateral perforation.

The manufacturer of the Essure device, Bayer, recently announced they would be halting sales of the implant at the end of 2018. However, some women are still opting for this method of sterilization. While the FDA backs the

safety and efficacy of the implant [6], it is still important to always discuss all the potential risks associated. This case report describes one such unusual complication: bilateral post-procedure migration. Providers should be aware that such complications may occur even in the absence of symptoms, especially in those patients lost to initial follow-up

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