Case Report

Essure Microinsert Abdominal Migration after Hysteroscopic Tubal Sterilization of an Appropriately Placed Essure Device: Dual Case Reports and Review of the Literature

Shadi Rezai, Meghan LaBine, Hunter Azdel Gomez Roberts, Isamarie Lora Alcantara, Cassandra E. Henderson, Malvina Elmadjian, and Dilfuza Nuritdinova

1Department of Obstetrics and Gynecology, Lincoln Medical and Mental Health Center, Bronx, NY 10451, USA
2School of Medicine, St. George’s University, St. George’s, Grenada

Correspondence should be addressed to Shadi Rezai; rezsha@sgu.edu and Dilfuza Nuritdinova; dilfuza.nuritdinova@nychhc.org

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Background. The Essure device is a method of permanent sterilization widely used in the US that has proven to be safe and effective in most cases. However, there have been reports of device migration that have led to failed tubal occlusion as well as several other serious complications resulting from the presence of the device in the abdominal cavity. Case. This paper represents two cases of failed tubal occlusion by an appropriately placed Essure device without signs or symptoms of further complications related to device migration. Conclusion. Although there have only been 13 reported cases of abdominal device migration since November 2014, this case indicates that the actual number may be higher than reported since it is possible for migration to occur without additional complications. In the majority of reported cases of abdominal migration a major complication requiring surgical correction occurred, such as adhesions, small bowel obstruction, bowel perforation, or persistent pelvic pain. To avoid these complications it is recommended that migrating implants be removed; however, this case also represents an example of when a migrating device may remain in situ in an asymptomatic patient.

1. Background

The Essure pbc (Permanent Birth Control System) device is a dynamic expanding microinsert that stimulates benign tissue growth when placed in the proximal section of the fallopian tube, eventually occluding the tube. The device was approved in 2002 as a means of permanent sterilization by the US Food and Drug Administration (FDA), and initial reports showed a high rate of safety and patient acceptability [1–4].

The benefits of the Essure hysteroscopic tubal occlusion/sterilization procedure are unique from other permanent birth control methods because it is hormone-free and does not require a skin incision [4, 5]. Essure placement can be done as an office based procedure since patients do not require general anesthesia, allowing recovery to be quicker than other types of sterilization [4, 5]. Most women can go home 45 minutes after the procedure and return to normal activity within one to two days [4, 5].

Upon placement of Essure, ideally 3 to 8 outer coils of the expanded Essure microinsert should be trailing into the uterus (Figure 6). A follow-up hysterosalpingogram (HSG) three months after placement of the device is a safe method of confirming satisfactory placement and tubal occlusion [4, 6, 7]. Unless the microinsert has a trailing length that is greater than 18 expanded outer coils, the microinsert should be left in place [2]. Two-dimensional ultrasound (2DUS) can also be used and is more time-efficient and equivalent to three-dimensional ultrasound (3DUS) in locating Essure contraceptive microinserts to ensure correct placement at the time of initial insertion and for periodic checks later [8, 9].

The Essure procedure is 99.83 percent effective at preventing pregnancy when used according to the approved
instructions for use based on five-year clinical study data [4, 5]. Despite the benefits of Essure hysteroscopic tubal sterilization, there are potential risks of this procedure as well. It is important to remember that no form of birth control should be considered 100 percent effective. Not all women will achieve successful placement of both inserts. Studies have shown that up to 9.6 percent of women could become pregnant within 10 years of undergoing hysteroscopic sterilization [10], and abdominal migration and tubal perforation are rare but recognized complications [3, 10]. Of the approximately 50,000 Essure insertion procedures performed between 1997 and 2005, there were 64 reports of unintended pregnancies to the manufacturer, most of which were attributed to failure to use alternative birth control methods prior to confirmation. Only 14 cases had been reported out of the 750,000 devices that had been placed to date, according to the US Food and Drug Administration. Case reviews suggest that several factors influence the likelihood of complications, including physician experience in placement and anatomical anomalies in the patient [3].

Device displacement has been reported in three cases complicated by laterally sited ostia, tubal resistance, or endometrial adhesions but displacement was also reported in five women who had uneventful procedures, such as our patient. In the majority of cases of abdominal displacement, the patients were asymptomatic and migration of the device was diagnosed at the 3-month follow-up HSG [3, 4, 7, 12–14]. Despite being asymptomatic, most physicians, and our second patient in this case report, elected to remove the displaced device. Generally this is easily done laparoscopically, with the exception of the cases reported by Mantel et al. and Belotte et al. where the device was implicated in causing small bowel obstruction and perforation [3, 12, 13]. Removal has therefore become the standard practice in management of device migration.

The first patient in this case, however, declined laparoscopic removal of the Essure device. This was observed to be a safe option by Kerin et al. [3, 15] who reported three cases of migrating Essure devices that were left in situ after noting that the pelvic organs were healthy and normal. They did not report any later complications for those patients [2, 3].

The cause of device migration is not fully understood in all cases. Some cases have been reported where displacement was due to uterine or tubal perforation, but there have also been cases where no signs of perforation were seen, as in the first patient highlighted in our report. It is suspected that migration in those cases occurred through the natural opening in the fallopian tube [3, 7, 12, 13].

In other reported cases it was observed that the left implant is more commonly implicated in migration than the right, suggesting that proper insertion of the device into the left tube by right-handed physicians may be difficult [3]; however, this is unproven and not likely to be the cause in the subject of this report because both implants failed to occlude the fallopian tubes.

4. Discussions

Abdominal displacement of the Essure pbc is a very rare complication.
Figure 1: Patient Number 1, hysterosalpingogram DX (HSG) on 5/23/13, showing proper Essure placement with bilateral tubal occlusion with no spillage of the contrast.
5. Conclusion

As of November 2014, there were only 14 cases of Essure abdominal migration in the literature [3]. In some cases it has caused a severe adverse event such as adhesion [13], pelvic pain [14], small bowel obstruction [15], or bowel perforation [12] requiring major surgery [3, 12]. There have been cases of tubal perforation after Essure placement for which ultrasound failed to diagnose [10]. However, in most cases, abdominal displacement of the microinsert is asymptomatic and does not induce tissue damage, such as in the patients indicated in this report [3]. This reinforces the importance of follow-up HSG six months after the Essure device has been placed, in addition to the three-month follow-up that is currently standard practice, in order to gain better insight into the incidence of device migration.

Incorrect position of Essure microinserts can be seen postoperatively, when the initial placement procedure was difficult. In these cases, it is recommended to perform a transvaginal ultrasound (TVU) or pelvic X-ray 4 weeks after the procedure or after the first vaginal bleeding. It is also recommended that removal of the migrating device should be performed as soon as possible [3]. Moreover, during presterilization counseling, the patient should also be completely informed about the risks of these rare but relevant complications, as well as about the surgical interventions that could be required to solve the complication [3]. Even in the setting of appropriately placed Essure microinserts patient may have persistent postprocedure pain, which is an indication that the microinserts should be removed surgically [14]. However, if the patient is asymptomatic, pelvic organs appear healthy, and the patient declines device removal; evidence has shown that the patient may continue to live
comfortably and without complications from the displaced device [2, 3].

**Conflict of Interests**

The authors did not report any potential conflict of interests.

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**References**


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