ULTRASONOGRAPHIC ASPECT OF THE PERMANENT FEMALE ANTICONCEPTIONAL DEVICE ESSURE® - CASE REPORT

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ABSTRACT

Essure® is a contraceptive method that acts through hysteroscopic tubal occlusion. The purpose of this case report is to show the ultrasound images of the Essure® device well positioned, as it is an unusual case in the daily practice in diagnostic imaging.

KEYWORDS: CONTRACEPTION, FEMALE CONTRACEPTIVE DEVICES, ULTRASONOGRAPHY, GYNECOLOGY, WOMEN'S HEALTH.

INTRODUCTION

Female sterilization, by ligation or tubal occlusion, is the most effective and used method for family planning in the world[1]. Methods for female sterilization include salpingectomy, tubal ligation, laparoscopic tubal occlusion and hysteroscopic tubal occlusion[2]. The latter, commercialized as Essure® by Bayer AG (Leverkusen, Germany), involves the insertion of nickel / titanium alloy coils containing polyethylene fibers in the fallopian tubes, which cause a fibrotic reaction to obstruct the tubes and prevent fertilization[3]. The presented advantages of the procedure include the the fact that there is no need for incisions and/or general anesthesia[4]. Figure 1 shows the device; figure 2 shows the intratubary position of the device and figure 3, the hysteroscopic aspect after implantation.

Figure 1 – The Essure® intratubary device.[5]

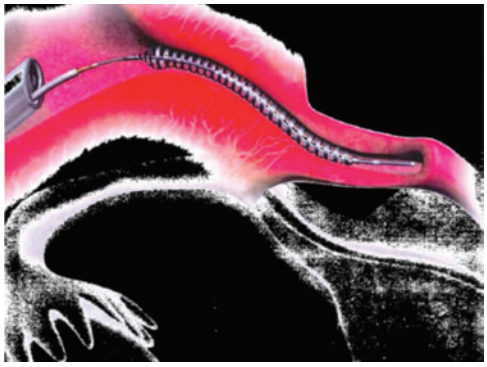

Figure 2 - Drawing showing placement of Essure®.

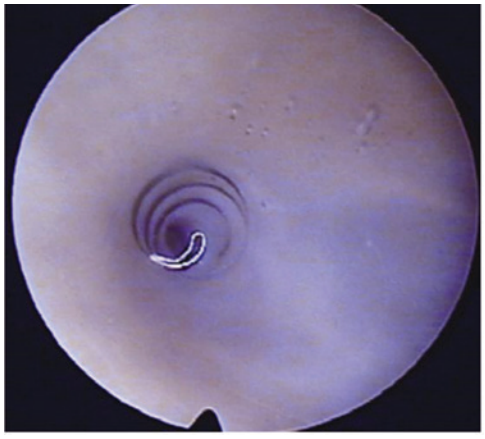

Figure 3 - Hysteroscopic appearance of Essure® after insertion.

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Essure®, by Bayer AG (Leverkusen, Germany) was the first mechanical device approved by the Food and Drug Administration (FDA), in 2002, for transcervical sterilization, and in 2009, the National Health Surveillance Agency (Agencia de Vigilancia Sanitária - ANVISA) approved it in Brazil[6].

The system consists of an intratubary device, a delivery system and a catheter to access each tube through transcervical route. The microdevice is a dynamic expansion spring composed of an inner ring of stainless steel surrounded by an outer ring of nickel and titanium that, being expandable, keeps the device at the uterus-tubal junction for the necessary time for fibrosis to occur.

Polyester fibers are around the central structure and cause a reaction of the surrounding tissue, followed by fibrosis, causing irreversible occlusion of the tubes. This process takes approximately three months and, during this period, the woman must maintain the contraceptive method she was previously using[7].

The review after implantation of the device is considered the final part of the procedure, being mandatory at three months, to verify if the implant is in the pelvis and in the appropriate position. In the United States, hysterosalpingography (HSG) is requested and, in other countries, a simple pelvic radiography or ultrasound is performed. If the devices are satisfactorily placed in the uterus-tubal junction, the patient can abandon the alternative method used for contraception. If the position is unsatisfactory, an HSG[8] is requested. However, transvaginal ultrasound performed three months after the insertion of Essure® showed the same accuracy as hysterosalpingography for detecting the correct positioning of the device[9].

The purpose of this case report is to show the ultrasound images of the Essure® device well positioned, as it is an unusual case in the daily practice of the ultrasonographer.

CASE REPORT

Asymptomatic female patient, 38 years old, undergoing routine exams. The ultrasound aspect of the Essure device, which is characteristically echogenic, is illustrated in the topography of the fallopian tubes, making it possible to assess its relationship with the adjacent soft tissue structures. As the serosa is well demarcated and easily identifiable, ultrasound allows the identification of the uterotubal junction, the point where the fallopian tube crosses the uterine serosa, which is an important anatomical landmark to assess the location of the Essure insertion. Figures 4, 5 and 6 show the position of the devices bilaterally.

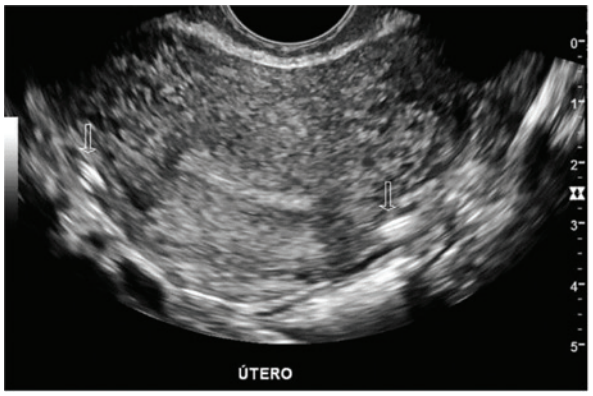

Figure 4 - Tubuliform echogenic image in the topography of the fallopian tubes, symmetrically and bilaterally identified at the uterotubal junction.

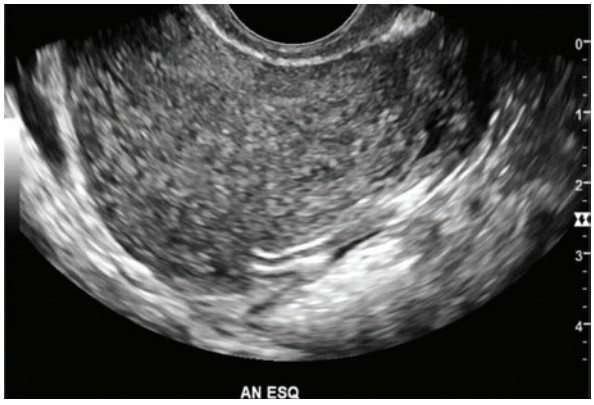

Figure 5 - Tubuliform echogenic image in the topography of the left uterine tube, evidenced as two parallel hyperechogenic lines.

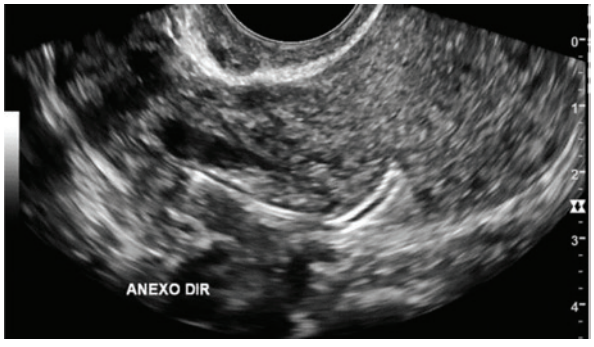

Figure 6 - Tubuliform echogenic image in the topography of the right uterine tube, shown as two parallel hyperechogenic lines.

DISCUSSION

Essure® revolutionized female sterilization by allowing definitive contraception through a rapid, minimally invasive and outpatient procedure, without the need for anesthesia, allowing a quick return to work and equally effective[10].

Several studies have confirmed the safety, effectiveness and low rate of adverse events of the technique; however, since 2013, the product has been the subject of controversy, with many women reporting complications requiring intervention[11]. In 2015, a review was published that confirms the similar effectiveness of Essure® in preventing pregnancy, but with a 10 times higher risk of reintervention, when compared to laparoscopic sterilization[12].

Since August 2017, the Essure® CE certificate of conformity has been suspended in the European Union by the National Standards Authority of Ireland, with Infarmed issuing a written statement in the same month recommending "as a precautionary measure, that the Essure® medical device should not be purchased or used during the suspension of the certificate"[13].

After several worldwide publications reporting possible adverse occurrences[14-16], in July 2018, Bayer decided to voluntarily discontinue the sale and distribution of the device until the end of December, in order to finalize its commercialization[17].

Ultrasonography is suitable for early post-insertion location, as the scan can ensure the correct positioning of the device and relieve the patient's anxiety, or even diagnose early malposition.

With this case, the importance of continuing education through diagnostic photographic documentation and the integration between ultrasonographers and gynecologists is emphasized.

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