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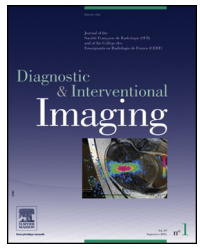

ORIGINAL ARTICLE /*Genito-urinary imaging*

Evaluation of tubal microinserts position using 3D ultrasound and pelvic X-ray

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Abstract
Purpose: To retrospectively compare three-dimensional ultrasonography (3D-US) and pelvic X-rays to assess the position of tubal sterilization microinserts.
Material and methods: Forty-four patients who underwent tubal sterilization with Essure® microinserts in our institution were included. The microinserts'position was evaluated three months after the procedure using 3D-US and pelvic X-rays. Placement on 3D-US was binary categorized as correct or incorrect and the distance between the two devices was reported. The orientation and symmetric deployment of the microinserts and the distance between the proximal parts of the two devices was assessed on pelvic X-rays. Performance of 3D-US and pelvic X-ray were compared using Mac Nemar test. Comparison of the distance between the two devices measured on pelvic X-rays and 3D-US was made with the paired Student *t* test.
Results: 3D-US images showed microinserts in 93% (41/44). Eighty-six percent (38/44) were correctly positioned on 3D-US and 82% (36/44) on pelvic X-rays. No significant differences between the performances of the two imaging techniques were found. No significant differences for the distance between the two devices measured on pelvic X-ray and 3D-US was found.
Conclusion: 3D-US is a simple, non-ionizing technique, which appears as a promising alternate technique to pelvic X-rays to assess the correct position of Essure® microinserts.

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Tubal sterilization is the most commonly used contraceptive method in the world [1]. Hysteroscopic sterilization is a well-tolerated procedure [1,2] avoiding general anaesthesia [3,4] and surgical incision [5] and the Essure® microinserts (Conceptus, Inc., San Carlos, CA, USA) were first approved in the USA in 2002 [6,7]. It is a permanent birth control device with an efficiency rate at 5-years around 99% [8—11].

Optimal positioning of the microinsert is needed to obtain fibrotic reaction and subsequent tubal occlusion. Consequently, correct position is usually ascertained three months after placement [6,12,13]. The imaging techniques used for ascertaining the correct position may vary among countries [13—17]. Hysterosalpingography (remains the gold standard and is currently recommended by the Food and Drug Administration (FDA) [18—21] whereas pelvic X-rays are recommended in Europe [12]. The new recommendations from the manufacturer advise to perform a pelvic X-ray in first intention three months after the procedure. Hysterosalpingography needs to be performed when the procedure is complicated or if pelvic X-rays do not confirm correct positioning of the devices.

According to Thiels et al. [17], two-dimensional (2D-US) and three-dimensional ultrasonography (3D-US) are excellent alternatives to pelvic X-rays or hysterosalpingography to confirm the correct position of the Essure coils 3 months after the procedure [17].

The purpose of our retrospective study was to compare the performance of pelvic X-rays with those of 3D-US to assess the position of Essure microinserts three months after hysteroscopic sterilization.

Materials and methods

Study population

This retrospective study was, approved by our institutional review board. Fifty-two women underwent hysteroscopic sterilization in our institution (University Hospital) between May 2010 and September 2012 inclusively. Patients were excluded if they underwent hysterosalpingography first because of complications or suspected failure during hysteroscopic procedure (1 patient), if they had history of unilateral salpingectomy (2 patients) or if 3D-US was not available for review (5 patients). Finally, 44 women who underwent 3D-US and pelvic X-rays were included in our study.

Tubal sterilization procedure

The sterilization procedure was carried out in an operating room without general anesthesia and in an ambulatory setting. The procedure was performed during the 7th—14th day of the menstrual cycle and a pregnancy test was conducted within 24 hours before the procedure [22].

A rigid hysteroscope, with a camera, was introduced into the uterine cavity and a saline solution was instillated to distend the uterus. Both tubal ostia were identified, and the microinserts were placed into the proximal portion of the fallopian tube using hysteroscopic guidance [12]; the devices were then deployed [22]. The gynaecologists considered that the Essure were correctly positioned when 3—8 coils were visible into the uterine cavity during hysteroscopy.

Imaging procedure

Pelvic X-rays and 3D-US were performed three months after hysteroscopic sterilization.

Plain anterior-posterior pelvic X-ray examination was performed under fluoroscopy and digital images were recorded.

Vaginal ultrasound was performed with a Voluson E8 (General Electric, Vélizy, France) and a 3D vaginal RC 5-9D probe. 2D-US was first performed to study the uterus' morphology, volume of the uterus, presence of uterine fibroids or adenomyosis, endometrial thickness and the ovaries.

Microinserts were identified in 2D mode and their relationship with the interstitial portion of the fallopian tubes and the uterus were analyzed. Maintaining the probe in a sagittal section of the uterus, we then realized a 3D acquisition. The 3D images allowed obtaining a coronal section of the uterus showing the two microinserts on the same image. If the two microinserts were not visualized in the same section, two coronal images were generated.

Hysterosalpingography (HSG) was secondly performed at least three months after hysteroscopic sterilization to verify tubal occlusion only when the microinserts appeared not correctly positioned on pelvic X-rays and/or 3D-US by the radiologist or when they were considered too proximal into the uterine cavity by the gynecologist who performed the hysteroscopic procedure.

An initial pelvic X-ray examination (Opera Swing, Numerix, Créteil, France) was performed before contrast agent administration. A catheter was then used to instillate 10 mL of iodinated contrast material (Hexabrix 320, Guerbet, Roissy-Charles de Gaulle, France, 10 mL) into the uterine cavity and digital images were recorded [18].

Image analysis

The reading of 3D-US, pelvic X-ray and hysteroscopy examinations was retrospectively done by one radiologist with four years of experience. In case of doubtful images a second radiologist with ten years of experience reviewed the images.

On pelvic X-ray examination, two parameters were evaluated. The first parameter was the orientation and symmetrical deployment of the devices on the basis of visualization of both devices in the pelvic area, horizontal orientation without angulation, and symmetrical appearance. The second parameter was the distance between the two proximal markers of the devices, which is normally <4 cm, which represents the average distance between the two tubal ostia.

On 3D-US, three parameters were studied.

The position of the microinserts was considered correct or incorrect (Fig. 1): a correct position consisted of a perfect position with an isthmic portion, an interstitial portion and an intra-uterine portion or a sub optimal position with an isthmic portion and an interstitial portion or with an interstitial portion and an intra-uterine portion. An incorrect position consisted of a distal position with a device into the distal portion of the fallopian tube without interstitial