

Original Article

Intraoperative Factors that Predict the Successful Placement of Essure Microinserts

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ABSTRACT **Study Objective:** To determine whether the number of coils visualized in the uterotubal junction at the end of hysteroscopic microinsert placement predicts successful tubal occlusion.

Design: Cohort retrospective study (Canadian Task Force classification II-2).

Setting: Department of obstetrics and gynecology in a teaching hospital.

Patients: One hundred fifty-three women underwent tubal microinsert placement for permanent birth control from 2010 through 2014. The local institutional review board approved this study.

Intervention: Three-dimensional transvaginal ultrasound (3D TVU) was routinely performed 3 months after hysteroscopic microinsert placement to check position in the fallopian tube.

Measurements and Main Results: The correlation between the number of coils visible at the uterotubal junction at the end of the hysteroscopic microinsert placement procedure and the device position on the 3-month follow-up 3D TVU in 141 patients was evaluated. The analysis included 276 microinserts placed during hysteroscopy. The median number of coils visible after the hysteroscopic procedure was 4 (interquartile range, 3–5). Devices for 30 patients (21.3%) were incorrectly positioned according to the 3-month follow-up 3D TVU, and hysterosalpingography was recommended. In those patients the median number of coils was in both the right (interquartile range, 2–4) and left (interquartile range, 1–3) uterotubal junctions. The number of coils visible at the uterotubal junction at the end of the placement procedure was the only factor that predicted whether the microinsert was well positioned at the 3-month 3D TVU confirmation (odds ratio, .44; 95% confidence interval, .28–.63). When 5 or more coils were visible, no incorrectly placed microinsert could be seen on the follow-up 3D TVU; the negative predictive value was 100%. No pregnancies were reported.

Conclusion: The number of coils observed at the uterotubal junction at the time of microinsert placement should be considered a significant predictive factor of accurate and successful microinsert placement. Journal of Minimally Invasive Gynecology (2017) 24, 803–810 © 2017 AAGL. All rights reserved.

Keywords: 3D transvaginal ultrasound; Essure microinsert; Hysteroscopic tubal obstruction; Hysterosalpingography

The Essure permanent birth control microinsert (Conceptus Inc. of Bayer AG, Whippany, NJ) is inserted via minimally invasive hysteroscopy and is approximately 99% effective in permanently preventing pregnancy [1]. Efficacy is based on the confirmed successful bilateral

placement in the fallopian tubes. Ideally, microinserts should be placed into the proximal section at the narrowest diameter of each fallopian tube [2,3]. Within 3 months local fibrous tissue induces occlusion of the tubes [4]. The Essure device is a dynamically expanding microinsert 4 cm long with 24 coils. According to the manufacturer's recommendations, 3 to 8 expanded outer coils should be left trailing into the uterus at the uterotubal junction for optimal positioning [5]. Implants that are too distally positioned in the fallopian tube or, on the contrary, too proximal may be expelled past the interstitial portion of the tube, which prevents tubal occlusion. Quality control of the Essure insertion should be possible during this

The authors declare that they have no conflict of interest.

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hysteroscopic procedure, by direct visualization of the microinsert at the uterotubal junction.

The US Food and Drug Administration currently recommends that the microinsert positions be checked 3 months after the placement procedure by transvaginal ultrasound (TVU) and/or by hysterosalpingography (HSG) as an alternative confirmation test for evaluating tubal patency [5,6]. Imaging used most frequently in Europe includes pelvic radiography and TVU. Ultrasound is a simple and satisfactory method for confirming microinsert position in most cases [3,4,7]. The contribution of 3-dimensional (3D) ultrasound helps to clarify the position of the microinserts within the proximal portion of each fallopian tube by providing a frontal view of the uterus [8,9]. Four positions are used to validate coil placement based on 3D ultrasound: perfect, proximal, distal, and very distal [10]. HSG is used to confirm tubal obstruction when the position found on ultrasound is very distal or if the microinsert is not visualized in the fallopian tube.

In our department a 3D TVU is always conducted 3 months after the procedure. This study questions whether such a systematic confirmation scan is necessary when operative criteria (visualizing 5 coils at the uterotubal junction) are met satisfactorily. The aim of this study is to determine whether the number of coils visualized in the uterotubal junction at the end of the placement procedure predicts the success of the procedure, which is proper positioning of the device.

Methods

Subjects and Screening

All consecutive Essure procedures performed from November 2010 through January 2014 in our tertiary university hospital were retrospectively analyzed. The local institutional review board approved this study.

Essure Placement Procedure

These outpatient procedures were carried out in the hospital operating room with patients under local anesthesia combined with intravenous sedation or under general anesthesia. We used a hysteroscope with a 5-mm outer diameter, a 30-degree oblique lens, and 5 French instruments. Preliminary dilatation of the cervix was not routinely performed, and the hysteroscope was introduced through the inserted speculum. The Essure microinsert for permanent birth control (ESS 305; Bayer, Leverkusen, Germany) was inserted after the identification of both uterotubal junctions. The team included 10 surgeon gynecology specialists, and most placement procedures were completed by the 2 most experienced surgeons.

Documentation of surgical details and placement success (appropriate releasing of the microinsert) or failure (unachievable release of the microinsert) was collected from patient medical records. The quality of visualization during

hysteroscopy was mentioned from the operative report using a 3-point Likert scale (good, average, or poor visualization). The operative report for all Essure placement procedures was standardized, and the number of coils visualized in the uterotubal junction at the end of hysteroscopy was recorded. In some cases there was also a photograph.

3D TVU Follow-Up

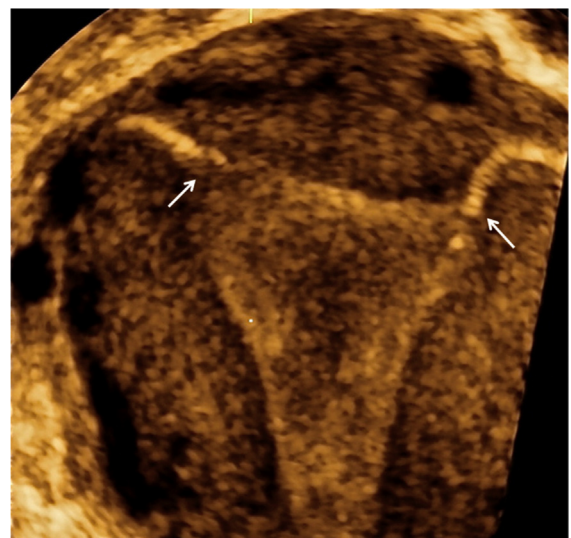
Two trained sonographers routinely performed the 3D TVU 3 months after the placement procedure to confirm tubal occlusion and ensure proper microinsert position at an appointment arranged before placement procedure hospital discharge. A Voluson E8 General Electric device (GE Medical Systems, Zipf, Austria) and a 3D transvaginal probe (RIC 5-9 MHz; GE Medical Systems) were used to obtain a slow scan (maximum quality), and the volume was set to volume contrast imaging mode to improve axial resolution (2-mm thick with an "x-ray" rendering mode, 100% volume contrast imaging).

The microinsert appears as an echogenic linear structure on the frontal uterine view (Fig. 1). 3D ultrasound allows for multiplanar reconstruction of the anatomy between the microinsert and the uterotubal junction. Four ultrasound positions were established [10]: an optimal position with intrauterine portion, cornual portion, and isthmic portion; a proximal position with intrauterine and cornual portion; a distal position with no intracavitary portion; and a very distal position when the microinsert was located beyond the isthmic portion of the fallopian tube.

Ultrasounds were reviewed by a blinded experienced sonographer to determine microinsert position. When the

Fig. 1

Frontal view of the uterus by 3D TVU. The microinsert on the left was in the optimal position and on the right was in the distal position (white arrows).



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