Is the 3D-US technique the future method of choice to accompany hysteroscopic sterilization to reassure women of a reliable birth control method?

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In this issue, a large series of three-dimensional ultrasounds (3D-US) assessing tubal occlusion after hysteroscopic sterilization with Essure microinsert is presented (Legendre, 2011). Is the 3D-US technique the future method of choice to accompany hysteroscopic sterilization to reassure women of a reliable birth control method?

The Essure birth control device was first introduced in 2001 and has since gained approval in several countries as an alternative to laparoscopic sterilization. According to a recently published state-of-the-art article, hysteroscopic sterilization has a low complication rate and the author states that the procedure should be preferred to abdominal procedures, provided the equipment and the experience required are available (Beerthuizen, 2010).

The commonly claimed advantages are that the procedure can be conducted in an out-patient setting, there is no need for general anesthesia and the technique avoids the risks of laparoscopy. The disadvantage compared with laparoscopic sterilization is that the procedure should be followed by an imaging test confirming tubal occlusion, 3 months after the initial procedure when the fibrotic process should be complete. The compliance with the hysterosalpingography (HSG) follow-up protocol is poor (Guiahi, 2010). Pregnancies occurring after Essure placements are often among those women who have deviated from the follow-up protocol. The cumulative pregnancy rate after 18 months has been reported to be 3.85/1000 women (Verseema, 2011). HSG has been the recommended diagnostic test, but in the search for alternatives avoiding radiation and/or patient discomfort, other techniques like ultrasound and pelvic radiography has been explored.

Pelvic radiography for the assessment of the positioning of microinserts after hysteroscopic sterilization cannot be recommended according to Veersema et al. (2010). Sensitivity and specificity were poor, as was the reproducibility, particularly if gynecologists performed the evaluation, when pelvic X-ray was compared with HSG as the reference standard.

Transvaginal ultrasound (TVUS) has been suggested as the first diagnostic test because it is minimally invasive and averts ionizing radiation (Verseema, 2011). In the Dutch protocol, TVUS was performed at 12 weeks if the Essure procedure was uncomplicated and successful, while HSG remained as the confirmatory test if the hysteroscopic procedure was difficult. This protocol reduced the number of HSG’s from 100 to 14% of all successful placements, without compromising the reliability of the sterilization.

Can 3D-US improve the diagnostic accuracy further? Legendre and co-workers present in this issue a retrospective case series of 227 patients in which 3D-US was used to assess the position of the Essure microinserts. The authors presented in a previously published paper, 40 cases in a prospective observational study in which 3D-US was evaluated for diagnostic accuracy with HSG as reference standard (Legendre, 2010). HSG showed tubal patency for three devices, all of which had been placed in a very distal position according to the 3D-US classification. The authors concluded that 3D-US is a simple and reproducible technique to assess the position of the Essure microinserts and appears to protect most patients from the negative aspects of pelvic radiography and of HSG. These 40 patients are also included in the present paper. Among 311 women who underwent hysteroscopic sterilization, 90% underwent imaging verification of the device 3 months later. The majority had 3D-US (n = 227) while 175 had pelvic radiography and 64 had HSG. This distribution of techniques does not allow the calculation of diagnostic accuracy with HSG as reference standard (Legendre, 2010). HSG showed tubal patency for three devices, all of which had been placed in a very distal position according to the 3D-US classification. The authors concluded that 3D-US is a simple and reproducible technique to assess the position of the Essure microinserts and appears to protect most patients from the negative aspects of pelvic radiography and of HSG. These 40 patients are also included in the present paper. Among 311 women who underwent hysteroscopic sterilization, 90% underwent imaging verification of the device 3 months later. The majority had 3D-US (n = 227) while 175 had pelvic radiography and 64 had HSG. This distribution of techniques does not allow the calculation of diagnostic accuracy with HSG as reference standard in the entire sample, only for a subset of 118 tubes. In this selected group, sensitivity and negative predictive value were 100%, while specificity was 77% and positive predictive value 21%. In addition, it was presented that 3D-US was appropriate for assessing device position in 86% of patients, implying that 14% would need a confirmatory HSG. This was statistically significantly lower than the proportion (26%) in need of an HSG after pelvic radiography.
These results should be viewed with some caution since the retrospective design is associated with both selection and verification bias. However, the results are interesting and provide promising data for the technique. Certainly, both the two-dimensional TVUS and the 3D-US techniques improve patient convenience as compared with HSG. In comparison with pelvic radiography, the ultrasound techniques show better diagnostic performance and obviously avoid ionizing radiation. Improved patient convenience can hopefully increase compliance to the follow-up protocol and thus increase the detection rate of inappropriately placed microinserts and decrease the number of unintended pregnancies.

Presently there are only two studies evaluating the efficacy of 3D-US assessing the position of microinserts compared with HSG as reference standard, both conducted by the same group and partly including the same patients. The level of evidence for 3D-US being efficacious is low and prospective studies are needed. Considering that both TVUS and 3D-US reduced the need for HSG to 14% in respective studies, a comparison between the two methods would be of interest (Verseema, 2011; Legendre, 2011). Another reason to support that study comparison is that the two-dimensional TVUS is still the most common technique available to gynecologists. The ultimate study design would then be a randomized trial in which patients were randomized to two-dimensional TVUS or 3D-US, followed by HSG, evaluated without prior knowledge of the ultrasound results. The question now become, who has the opportunity, ability and will to perform such a study!

References


