Noncompliance Is Key to Essure-Related Pregnancies

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CHICAGO — Data indicate that most pregnancies in women who undergo the Essure hysteroscopic sterilization procedure could be avoided, Dr. John F. Kerin said at the annual meeting of the AAGL (formerly the American Association of Gynecologic Laparoscopists).

There have been no pregnancies with the Essure device (Conceptus, San Carlos, Calif.) in multicenter phase II or pivotal trials after 4 years of follow-up. But in postmarketing use, there have been 37 reported pregnancies following an estimated 29,736 procedures from 1997 to December 2004, said Dr. Kerin, a consultant and principal clinical investigator for Conceptus. As of October 2005, 52 pregnancies had been reported in 40,568 procedures worldwide.

Data analysis through 2004 suggests pregnancies are occurring after the device is put into general practice because of noncompliance with protocol by the physician or patient (21 cases, 57%); the patient was probably pregnant before the procedure (6 cases, 16%); or the hysterosalpingograms were misread (6 cases, 16%). Four cases (11%) were due to other etiologies: expulsion of the device with an earlier noncommercially available design, and a device expulsion. Two are still being investigated.

"The important thing is there were no confirmed Essure device–related failures resulting in pregnancy amongst tens of thousands of women so far who have had this procedure worldwide," Dr. Kerin said. "I think most pregnancies are avoidable, and we need to up-skill and use our care before the procedure, during the procedure, and in the follow-up."

Among the 21 noncompliance cases, 17 patients didn't return for follow-up at 3 months. These failures were related to errors that could have been identified at the postplacement exam, such as failure of long-term bilateral placement (12), unilateral device expulsion (6), and perforation (3). Three other cases of failure to place one of the devices were not followed up and alternative contraception was not provided.

"Why a doctor would fail to provide alternative contraception following an incomplete sterilization is beyond me," said Dr. Kerin, professor of reproductive medicine at Flinders University, Adelaide, Australia. He advised physicians to ensure that their patients are using reliable birth control before and after device placement, and to perform the procedure prior to ovulation to avoid the risk of luteal phase pregnancy.

"Beware of the patient who is not on reliable contraception who may be using condoms only or the 'safe method' and you choose to do that procedure after ovulation," he said. "The patient may already have an embryo in that fallopian tube just ready to pop into the uterus when you are doing the procedure and [that would] therefore sabotage the outcome."

Physicians should also always follow the instructions for correct Essure device placement and hysterosalpingogram protocols, educate their patients on the necessity of follow-up, and review the complete radiology report and all films themselves.

Even during this introduction of a new technique, the failure rate with Essure is comparable with the established laparoscopic methods of sterilization, with the distinct advantage of avoiding incisional surgery and general anesthesia, he said. ■

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