Five Pregnancies Reported in Essure’s First Year

After the device was approved by the Food and Drug Administration in 2002, Conceptus Inc. of San Carlos, Calif., shipped 9,000 units of Essure in the first year of commercial availability, said Dr. Brill, who is professor of ob.gyn., and director of gynecologic endoscopy at the University of Illinois, Chicago.

“Essure and other hysteroscopic sterilization methodologies are quickly becoming a standard option for patients seeking permanent sterilization and probably will become the norm, by my prediction, in 2 or 3 years,” Dr. Brill said. “The effectiveness rate remains high in the commercial marketplace.”

The rates of various adverse events reported in that first year were lower than those reported during the pivotal premarket clinical trials, but Dr. Brill acknowledged that the actual number of adverse events—and pregnancies—may be higher than the number voluntarily reported to the company by clinicians.

For example, the rate of expulsion of the Essure microinserts was 0.16% in commercial experience, compared with 2.9% in the clinical trials.

Tubal perforations were 0.11% in commercial experience and 1.1% in clinical trials.

Clinicians also reported that 0.97% of women who attempted to become pregnant experienced miscarriages, resulting in deployment difficulties.

Dr. Brill discussed the five pregnancies in detail.

The first case was of a woman who appeared to have had an adequate bilateral placement, but she failed the hysterosalpingogram (HSG) 3 months later. When she had a subsequent laparoscopic tubal ligation, it was discovered that one of the microinserts had been expelled.

The second case involved a unilateral placement, but the physician mistakenly believed the woman had a unicornsate uterus and placed only one unit. In fact, she had a normal bicornuate uterus and had an intact fallopian tube remaining.

The woman, too, failed a 3-month HSG. In the third case, the inserts were placed bilaterally in a woman who had a conceptus in situ and a documented luteal pregnancy.

In the fourth and fifth cases, placement of the devices was bilateral, but on review, it turned out there was subsequent misreading of radiographic criteoria.

In one case, the clinician apparently misread the HSG, which other reviewers later determined did indeed document a coronal perforation.

In the other case, the problem was a misplaced three-dimensional ultrasound, which on review documented a misplaced pelvic device. Although physicians in the United States don’t use 3D ultrasound to document a misplacement, the microinserts in the Europe, the technology is used for this purpose.

Although Dr. Brill did acknowledge receiving consulting and grant support from several companies, including TAP Pharmaceuticals, Gynecare, SurgiX, Gyrus Medical, and ACM, this list did not include Conceptus, which distributes Essure.

For more information, see the annual San Antonio Breast Cancer Symposium.

Next Issue: Cancer Update

We’ll bring you coverage of the annual San Antonio Breast Cancer Symposium.