

Sterilization Inserts Appear Easy to Implant

BY MICHELE G. SULLIVAN

KISSIMMEE, FLA. — The third generation of a hysteroscopic sterilization microinsert is quick and simple to deploy, with a negligible rate of adverse events due to nickel hypersensitivity reactions, two postmarketing studies have concluded.

Both newly trained and experienced physicians had at least a 97% success rate for placing the Essure 305 inserts in both fallopian tubes, Dr. Mark Levie reported at the annual meeting of the AAGL.

"The only significant difference we saw was that experienced physicians [who had done at least 25 placements] completed the procedure in 8 minutes, significantly faster than newly trained physicians," said Dr. Levie of Montefiore Medical Center, New York.

The first postmarketing study, required by the Food and Drug Administration and sponsored by Conceptus Inc., which manufactures the implants, ex-

amined successful bilateral placement rates in 578 women. The procedures were performed by 37 physicians who were newly trained in placing the implants and 39 physicians who had placed at least 25 of them.

The study began in 2007; the FDA terminated it early in March 2009, after a preliminary analysis determined that enrolling more women would not significantly change the placement rate.

The patients' mean age was 35 years; their mean body mass index was 29 kg/m². About one-third of them had undergone at least one abortion. Mean parity was two.

Among the 578 women, there were 562 successful bilateral placements, 10 unilateral placements, and 6 bilateral failures, resulting in an overall success rate of 97%.

VITALS

Major Finding: Both newly trained and experienced physicians had at least a 97% success rate for placing the Essure 305 inserts in both fallopian tubes in one postmarketing study. The rate of adverse events due to nickel hypersensitivity was lower than expected in a second study.

Data Source: The first postmarketing study included 578 women. The second postmarketing study looked at nickel hypersensitivity.

Disclosures: Dr. Levie and Dr. Zurawin are both on the medical advisory board of Conceptus Inc. Dr. Levie also serves as a physician educator for the company.

Parity, mode of delivery (cesarean section vs. vaginal), prior surgery, prior abortion, and body mass index did not significantly affect placement rate. Age was a factor; the average age of the patient with a successful placement was 35 years, significantly younger than the average age for patients with unsuccessful placement (39 years).

Novice physicians and experienced physicians had similar success rates (97% vs. 98%).

The mean placement time was 9 minutes, with experienced physicians placing the microinserts an average of 2 minutes faster than novice physicians.

"Ninety-five percent of the cases were completed in less than 20 minutes, and 71% were done in an office setting," Dr. Levie said.

The inserts are composed of stainless steel and nitinol, both of which contain nickel, Dr. Robert Zurawin said at the meeting. Nickel hypersensitivity is a contraindication for placement in the United States; in Europe, there is a warning against placing the inserts in patients allergic to the metal.

To date, 330,000 of the devices have been implanted in women worldwide,

with 23 reports of adverse events due to nickel hypersensitivity, said Dr. Zurawin of Baylor College of Medicine, Houston.

The rate is much lower than might be expected given the background rate of nickel hypersensitivity, he said. "Between 10% and 15% of the female population is allergic to nickel, and that rate is higher in younger women than it is in older women," he said.

To investigate the events, Dr. Zurawin conducted a retrospective study of adverse events reported in Essure's phase II clinical trial and a pivotal trial that included 518 women. He also included reports of nickel-related adverse events in the FDA's MAUDE database and Conceptus's adverse event reporting system.

No nickel-attributed adverse events were reported in the phase II trial or the pivotal trial, Dr. Zurawin said. Symptoms of the postmarketing events included rash, hives, pain, cyanotic extremities, cramping, dizziness, nausea, fatigue, confusion, and headaches.

Only one patient had a confirmed nickel allergy, and three had positive nickel hypersensitivity skin tests. The patient with a confirmed nickel allergy was asymptomatic.

Of those with a positive skin test, one complained of a rash on her thighs where she had been washed with an iodine-containing antiseptic. One complained of postprocedural nausea, shivering, and discomfort; the inserts were removed 8 months later with nothing remarkable observed at that time. One patient went to the hospital with pain, rash, and hives after the procedure; the inserts were removed, and pathology noted white blood cells and eosinophils around them.

"This is one case where nickel allergy is a reasonable assumption," Dr. Zurawin said. ■

Children Conceived by IVF Showed No Red Flags in Behavior

BY PATRICE WENDLING

ATLANTA — Children conceived with in vitro fertilization have the same number of parent-reported abnormal childhood behaviors as those conceived naturally, based on a retrospective cohort study of 213 5-year-olds.

The prevalence of any abnormal behavior on the validated Child Behavior Checklist was not significantly different at 10.5% for children conceived with IVF versus 10.2% for those conceived without IVF ($P = .9$; odds ratio, 1.03).

There also were no significant differences between groups in the prevalence of individual abnormal behaviors, Dr. Thomas Molinaro reported in a poster at the annual meeting of the American Society for Reproductive Medicine. Some of the behavioral domains assessed in the IVF and unassisted groups were anxiety (2.9% vs. 4.7%), attention (1.9% vs. 0.9%), social behavior (0% vs. 1.8%), aggression (1.9% vs. 0.9%), and depression (1.9% vs. 2.8%).

"I'm reassured that at least there's no huge signal jumping out, even with the small sample size that we have," Dr. Molinaro said during a press briefing at the meeting. "It's not like there's a twofold difference in either direction."

"While the factors involved in childhood development are complex, it is likely that any contribution of assisted reproductive technology is negligible or subtle," Dr. Molinaro, a reproductive endocrinologist at the University of Pennsylvania in Philadelphia, and his associates wrote.

The 105 IVF-conceived children and 108 control children were not different in terms of pregnancy complications (19% vs. 15%), birth weight (3,476 g vs. 3,534 g), or gestational age (39.1 vs. 39.6 weeks). ■

VITALS

Major Finding: The prevalence of any abnormal behavior was not significantly different for children conceived with IVF versus those conceived without IVF.

Data Source: A retrospective cohort study of 213 5-year-olds.

Disclosures: The study was supported by a National Institutes of Health grant. Dr. Molinaro and his associates disclosed no conflicts of interest.

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