Implanon's Efficacy in Obese Women Is Unknown

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MIAMI BEACH — Nearly a year following its approval, the advantages and disadvantages of a contraceptive implant are becoming better known, but there are still no data on its efficacy in overweight or obese women, according to a presentation at an ob.gyn. conference sponsored by the University of Miami.

The Food and Drug Administration cleared Implanon (Organon International) for marketing in July 2006. It is the first single-rod, 68-mg etonogestrel, subdermal implant. The core is 40% ethylene vinyl acetate, which provides a slow, steady release of progestin for up to 3 years, according to clinical trials.

However, overweight and obese women were excluded from the preapproval studies. "This is kind of the kicker—efficacy in overweight women," Dr. Paul M. Norris said. "There are no clinical trial data." Women who weighed more than 130% of their ideal body weight were not studied. For physicians, such an exclusion would be "very impractical" in the United States, Dr. Norris added.

Implanon replaces the six-rod Norplant device, which was removed from the market following reports of product migration and side effects, Dr. Norris said. "The data on Norplant suggested it was still efficacious, although less so, in overweight patients. But I am not sure you can apply this finding to Implanon."

Implanon is inserted in the subepidermal groove of a woman's arm between her biceps and triceps, about 6-8 inches up from the crux of elbow. Physicians can order Implanon only upon completion of a training program, sponsored by the manufacturer, on insertion and removal. "They were concerned about injections in other vital structures. So far, the programs have gone well," said Dr. Norris, who is on the obstetrics and gynecology faculty at the University of Miami. He is on the speakers' bureau for Organon.

"The device to insert the implant looks like the Depo Provera syringe," Dr. Norris said. "The blue placebo injector for practice has a pregnancy rate of about 85% so make sure you are using the white injector with the active ingredient!"

Insertion time is faster than the Norplant, about a mean of 1 minute, compared with 4 minutes for the Norplant, Dr. Norris said. The 4-cm-long, 2-mm-diameter Implanon rod is not radiopaque. "If you lose an implant, you cannot palpate it 3 years later," he said. "It is very easy to pick up on ultrasound, but you need at least a 10-MHz wand, which is not common in most ob.gyn. offices," he said.

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Implanon's contraceptive effects are reversible—a woman's fertility quickly returns after removal, according to the manufacturer.

The mean removal time for Implanon is 3 minutes, compared with 11 minutes for Norplant, Dr. Norris said. "This is the mean, and some cases can take almost an hour, and you end up saying words you wouldn't normally say." In clinical trials, 1% of 923 participants experienced complications at implant insertion and 1.7% had complications at implant removal.

Contraindications include a known or suspected pregnancy. "It likely won't hurt the pregnancy, but it will not prevent a pregnancy if it is already there," Dr. Norris said. History of or current thrombotic disease, history of breast cancer, hepatic tumors, active liver disease, and undiagnosed abnormal genital bleeding are other contraindications. "Make sure there is nothing serious going on before you place the Implanon."

Bleeding changes were the most common reason women chose to stop Implanon treatment in clinical trials (cited by 11% of participants). Irregular bleeding and spotting is a common side effect, Dr. Norris said. In the studies, patients using Implanon reported an average of 18 days of bleeding or spotting every 90 days. "The problem is this is unpredictable," he said. "With the pill or patch, you have a better idea when to anticipate bleeding or spotting." ■