Higher rates of pain, bleeding found with Essure birth control device

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(HealthDay)—The permanent birth control device Essure is associated

with higher rates of chronic lower abdominal or pelvic pain and abnormal uterine bleeding compared with tubal ligation, according to interim results of a postmarket study ordered by the U.S. Food and Drug Administration.

The researchers compared Essure and tubal ligation among more than 1,100 women across the United States and found that rates of chronic lower abdominal or pelvic pain were just over 9 percent in the Essure group and 4.5 percent in the tubal ligation group, and rates of abnormal uterine bleeding were 16.3 percent in the Essure group and 10.2 percent in the tubal ligation group, *CNN* reported.

The Essure group had higher rates of gynecologic operations—including surgery to remove the device—than the tubal ligation group, while pregnancy rates were similar in the two groups, according to a statement from Terri Cornelison, M.D., director of the FDA Health of Women Program.

In 2018, Essure maker Bayer pulled the device from the U.S. market due to concerns about side effects. The FDA told Bayer to extend a postmarket surveillance study on Essure from three to five years, *CNN* reported. The study is ongoing, and patients are still completing one-year follow-up visits, the FDA said.

"As the FDA itself notes: 'This study is ongoing and the results are interim. Final analyses of end points will not be completed until the study concludes' in 2025. It is therefore too early to draw any conclusions," Bayer said in a statement, *CNN* reported. "The results of several large, real-world observational studies comparing patients with Essure to patients who have had tubal ligations consistently show that Essure's safety profile is similar to that of tubal ligation."

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