2011 FDA safety message tied to drop in transvaginal mesh use

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(HealthDay)—A 2011 U.S. Food and Drug Administration safety

communication correlated with a significant decline in transvaginal mesh use for treatment of apical prolapse, according to a study published online Sept. 10 in *Obstetrics & Gynecology*.

William D. Winkelman, M.D., from Mount Auburn Hospital in Cambridge, Massachusetts, and colleagues conducted a retrospective study of 36,523 surgical cases to examine the effects of the FDA safety communication and reclassification of transvaginal mesh to a class III device on national trends in apical prolapse treatment.

The researchers found that when stratified by surgical approach, there were no clinically meaningful differences in postoperative complications. From 2008 to 2017, there was a decrease in the use of transvaginal mesh from 35 to 11 percent. A decrease was noted in the proportion of apical procedures using transvaginal mesh of 4.4 percent per quarter in the year immediately after the first FDA safety communication in 2011; increases were seen in the proportion of intraperitoneal, extraperitoneal, and abdominal colpopexy. The greatest increase (2.6 percent per quarter) was seen for abdominal colpopexy procedures. No significant change was observed in the proportion of apical procedures using transvaginal mesh in the year following FDA reclassification of transvaginal mesh in 2016.

"We used the FDA statements as indicators of changes in perspectives on the use of transvaginal mesh, but we acknowledge that, in the years leading up to the FDA statements, there were reports of complications, which may also have contributed to the changing clinical practice," the authors write.

One author disclosed financial ties to the medical technology industry.

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