Study looks at impact of FDA safety alert on morcellation

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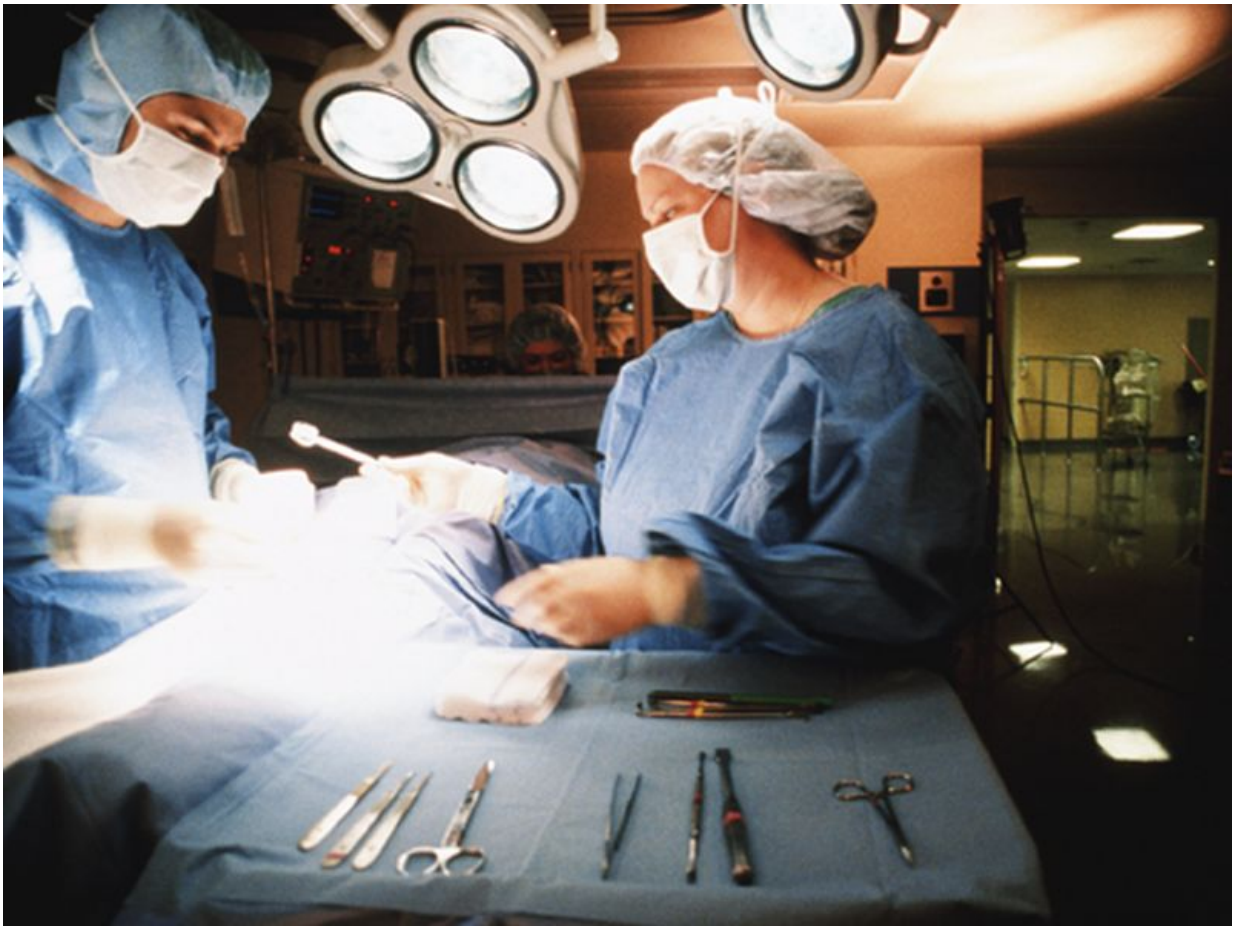

(HealthDay)—The use of minimally invasive hysterectomy decreased

and postoperative complications increased following the U.S. Food and Drug Administration safety communication discouraging use of laparoscopic power morcellation during hysterectomy or myomectomy for treatment of uterine fibroids, according to a study published in the January issue of the *American Journal of Obstetrics & Gynecology*.

John A. Harris, M.D., from the University of Michigan in Ann Arbor, and colleagues conducted a retrospective cohort study to examine temporal trends in surgical approach to hysterectomy and postoperative complications before and after the FDA safety communication. During the study period there were 18,299 hysterectomies available for analysis.

The researchers found that in the eight months after the safety communication, use of laparoscopic hysterectomies decreased by 4.1 percent (P = 0.005) and abdominal and vaginal hysterectomies increased by 1.7 and 2.4 percent, respectively (P = 0.112 and 0.012, respectively), compared with the 15 months preceding the safety communication. After the safety communication there was a significant increase in major surgical complications not including blood transfusions (P = 0.015), and the rate of hospital readmission within 30 days also increased (P = 0.025). There was no significant change in the rate of all major surgical complications or hospital reoperation after the safety communication (P = 0.177 and 0.593, respectively).

"Following the April 2014 FDA safety communication regarding power morcellation, utilization of minimally invasive hysterectomy decreased, and major surgical, nontransfusion complications and 30-day hospital readmissions increased," the authors write.

More information: Abstract
Full Text (subscription or payment may be required)