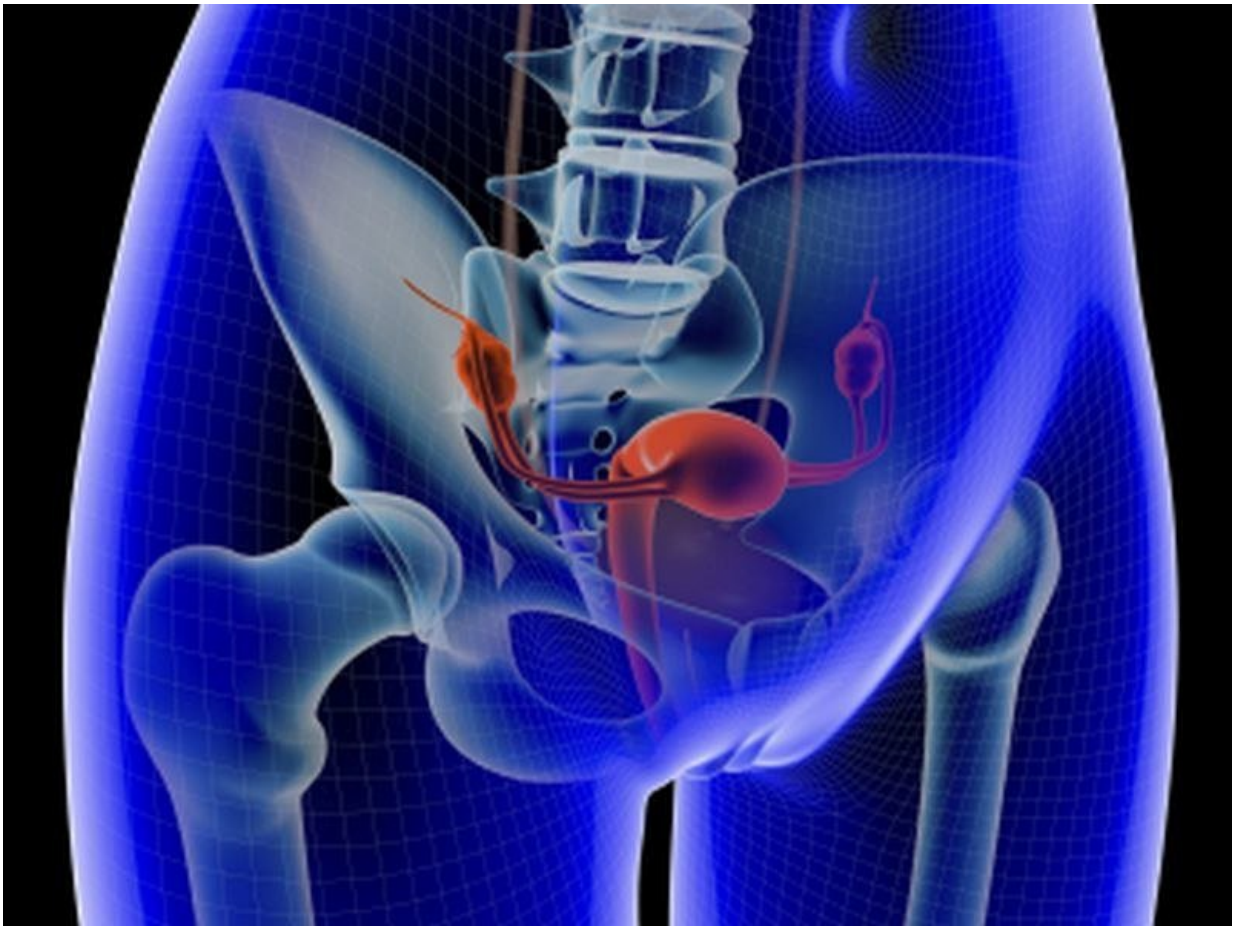
FDA warning ups hysterectomy complications for uterine fibroids

April 12 2018



(HealthDay)—For women undergoing hysterectomy for uterine fibroids,

there was an increase in major and minor 30-day complication rates following the issuing of a U.S. Food and Drug Administration black box warning against the use of power morcellation for excision of uterine fibroids, according to a study published online April 11 in *JAMA Surgery*.

Francesco Multinu, M.D., from the Mayo Clinic in Rochester, Minn., and colleagues examined the changes in the rates of 30-day major and minor complications of hysterectomy for benign gynecologic indications before and after the FDA-issued warning. Data were reviewed from 603 hospitals between Jan. 1, 2013, and Dec. 31, 2015, for 75,487 women who underwent hysterectomy for benign gynecologic complications, including 25,571 who underwent hysterectomies with indication of uterine fibroids.

The researchers found that major and minor complications remained stable overall before and after the warning. Among the women who underwent hysterectomy for uterine fibroids, there was a significant increase in major complications (from 1.9 to 2.4 percent; adjusted odds ratio, 1.23) and minor complications (from 2.7 to 3.3 percent; adjusted odds ratio, 1.21). In this subgroup there was an increase in the rate of open abdominal surgery (from 37.2 to 43.0 percent), and a significant decrease in the rate of minimally invasive surgery (from 56.1 to 49.7 percent).

"Regulatory bodies and medical societies should consider these findings when issuing relevant communications," the authors write.

More information: Abstract/Full Text