VITALS

Major Finding: The specificity of a new screening approach developed for postmenopausal women at average risk for ovarian cancer was 99.9%.

Data Source: A single arm, prospective, multi-center study of 3,252 women aged 50-74.

Disclosures: One of the study authors, Dr. Herbert A. Fritsche, disclosed that he received research funding from Roche Diagnostics. Another study author, Dr. Robert C. Bast, Jr., disclosed that he serves as a consultant and advisor to Fujiresio Diagnostics, Inc. He also receives other remuneration and royalties for helping to invent the CA-125 assay.

vaginal ultrasound and referral to a gynecologic oncologist."

After following the women for 9 years the researchers found that the average annual rate of referral for CA-125 assays every 3 months was 6.8% and that the average annual rate of transvaginal ultrasound and referral to a gynecologic oncologist was only 0.9%. "Each year the overwhelming majority of women were triaged to the low-risk category—an annual CA-125," Dr. Lu said.

Cumulatively, 85 women (2.6%) received transvaginal ultrasound and subsequent referral to a gynecologic oncologist. Of these, eight required surgery: three for invasive ovarian cancers (two stage 1C and one stage IIB), two for borderline ovarian tumors, and three for benign ovarian tumors. This translated into a positive predictive value of 37.5%. "This means that three operations would be necessary to detect one case of invasive ovarian cancer," she said.

The combined specificity of ROCA followed by transvaginal ultrasound was 99.9%, "which means that there were very few false positive."

Dr. Lu emphasized that while results of the ROCA screening strategy are encouraging, "they are not practice changing at this time. We need to await the results of a definitive ovarian cancer screening trial that uses mortality as an end point, and uses the same ROCA algorithm." That trial of more than 200,000 women is underway in the United Kingdom, she said. Results are expected in 2015.

ASCO President Dr. Douglas W. Blayney said that the ROCA algorithm "represents yet another example of personalized medicine. Here, we have a personalized screening strategy for a vicious type of cancer. This also represents a more refined application of known technology. The CA-125 is widely available, as is transvaginal ultrasound, which is intrusive and technologically somewhat difficult to interpret. Here, we have a staged application." ■

FDA Warns on Fracture Risks With PPIs

The Food and Drug Administration issued a warning to physicians and consumers that proton pump inhibitors may increase the risk of hip, wrist, and spine fractures.

The agency said that it is changing the labeling for prescription and over-the-counter versions of proton pump inhibitors (PPIs) to reflect new safety information that is the result of a review of seven epidemiologic studies. Most of the observed risk was in people older than age 50 years and those who took high doses or used the drugs for more than a year. Prescription PPIs include esomeprazole (Nexium), dexlansoprazole (Dexilant), omeprazole (Prilosec, Zegerid), lansoprazole (Prevacid), pantoprazole (Protonix), and rabeprazole (Aciphex). There are OTC versions of Prilosec, Zegerid, and Prevacid.

"Because these products are used by a great number of people, it's important for the public to be aware of this possible increased risk and, when prescribing proton pump inhibitors, health care professionals should consider whether a lower dose or shorter duration of therapy would adequately treat the patient's condition," said Dr. Joyce Korvick, deputy director for safety in FDA's Division of Gastroenterology Products, in a statement.

The FDA did not have access to the raw data in the studies; it merely reviewed what was published. But, said the FDA, it accepted the results because the studies appear to be well designed. Even so, those studies had limitations, and there is still no understanding of why PPIs might lead to fractures.

—Alicia Ault

The full agency communication is located at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm213206.htm.