Algorithm Predicts Epithelial Ovarian Cancer Risk

BY JANE SALODOF MACNEIL

SAN ANTONIO — A novel algorithm has been shown to be more sensitive than a widely used risk of malignancy index for predicting epithelial ovarian cancers in women who present with a pelvic mass or ovarian cyst.

The Risk of Ovarian Malignancy Algorithm (ROMA) stratifies women as being at high or low risk for epithelial ovarian cancer based on menopausal status and preoperative serum levels of two biomarkers: human epididymis protein 4 (HE4) and cancer antigen 125 (CA 125). Investigators found that the algorithm correctly classified 94% of women with epithelial ovarian cancer in a prospective, double-blind, multicenter trial with 457 evaluable patients (Gynecol. Oncol. 2009;112:40-6).

A new secondary analysis of trial data comparing patients with benign disease and all stages of epithelial ovarian cancer determined ROMA's sensitivity to be 94.3%, vs. 83.7% for the risk of malignancy index (RMI), when specificity for both was set at 75%. ROMA also was more sensitive than RMI in a comparison of patients with benign disease, tumors with a low potential for malignancy, and epithelial ovarian cancer (89% vs. 80.7%).

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DR. MOORE

"This tool can be used to triage patients to physicians and centers that are experienced in the care and management of patients with ovarian cancer," Dr. Richard G. Moore said at the annual meeting of the Society of Gynecologic Oncologists.

High-risk women should be referred to gynecologic oncologists and centers that have been shown to treat ovarian cancer with better survival outcomes and less morbidity, according to Dr. Moore. Low-risk women do not need that level of care and may be treated in their communities.

The investigators do not see ROMA as replacing the Society of Gynecologic Oncologists'/American College of Obstetricians and Gynecologists' referral guidelines for pelvic masses, he said in response to a question during a discussion of the study. Rather, Dr. Moore and his associates would like to see ROMA incorporated into the guidelines.

"Clinical findings and impressions are very important, but I think these markers can really help us to triage these patients," said Dr. Moore of Women and Infants Hospital and Brown University, both in Providence, R.I.

The investigators compared ROMA vs. RMI because the latter is a validated, well-accepted tool that is currently in use, he added in an interview. The RMI is based on menopausal status, CA 125 levels, and ultrasound scores of 0-5.

ROMA has two formulas, one for premenopausal and another for postmenopausal women. Both include HE4 and CA 125 levels, but the premenopausal formula weighs HE4 more heavily. "In premenopausal patients, there are many benign diseases that cause elevated CA 125, and there is no cancer," Dr. Moore explained, describing the two markers as complementary.

The algorithm was developed based on pooled data from a pilot study at Women and Infants Hospital and a retrospective case-control study at Massachusetts General Hospital in Boston. The prospective trial enrolled 566 women, who presented at 12 centers with pelvic masses that were documented on imaging and for which surgery was planned.

The investigators did not report sensitivity by histology, but Dr. Moore said it was close to or at 100% in all but mucinous tumors. ROMA was much less sensitive in mucinous tumors, identifying only about half of them, he said.

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