The OVA1 test improves the preoperative assessment of ovarian tumors

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Objective: OVA1 is an in vitro diagnostic multivariate index assay (IVDIMA) that combines five immunoassays into a single numerical result, including CA125 II, transthyretin (prealbumin), apolipoprotein A1, β2-microglobulin, and transferrin. Our objective was to evaluate the performance of OVA1 in the preoperative assessment of ovarian tumors.

Methods: OVA1 was evaluated in women scheduled for surgery for a known ovarian tumor in a prospective, multi-institutional trial involving 27 primary care and specialty sites throughout the United States. Preoperative serum was collected, and the OVA1 results were correlated with the physician assessment and surgical pathology. The preoperative malignancy assessment was documented by the enrolling physician after consideration of all available clinical information. Women were excluded from analysis if surgery was not performed, pathology report was not available, or blood specimen was improperly processed.

Results: The study enrolled 590 women, and 516 were evaluable with a presurgical assessment. Fifty-two percent were enrolled by non-gynecologic oncology (GO) surgeons. There were 151 ovarian malignancies (29.3%), including: 96 epithelial ovarian cancers (EOCs), nine nonepithelial ovarian malignancies (non-EOCs), 28 tumors of low malignant potential (LMP), and 18 malignancies metastatic to the ovary (met). The 235 premenopausal women enrolled (45.5%) accounted for 42 ovarian malignancies. The OVA1 test had the following performance: sensitivity 92.5%, specificity 42.8%, positive predictive value (PPV) 42.3%, and negative predictive value (NPV) 92.7%. OVA1 significantly improved the clinician's presurgical assessment for both non-GO and GO physicians. Sensitivity improved from 72.2 to 91.7% (95% CI = 83.0–96.1) for non-GO and from 77.5 to 98.9% (95% CI = 93.9–99.8) for GO physicians. The NPV improved from 89.1 to 93.2% (95% CI = 85.9–96.8) for non-GO and from 85.5 to 97.6% (95% CI = 87.7–99.6) for GO physicians. In addition, OVA1 correctly identified 70% (non-GO) and 95% (GO) of malignancies missed by preoperative physician assessment alone. The OVA1 sensitivity by histologic subtype was: EOC 99.0% (95/96), non-EOC 77.8% (7/9), LMP 75.0% (21/28), and met 94.4% (17/18).

Conclusions: The OVA1 test significantly improved sensitivity and correctly identified the majority of patients with ovarian malignancies that were missed by preoperative physician assessment alone. These data support the use of OVA1 in women scheduled for surgery for an ovarian tumor, to facilitate surgical planning and decisions about referral to a gynecologic oncologist before surgery.