

The Effect of Ovarian Imaging on the Clinical Interpretation of a Multivariate Index Assay

Goodrich ST, Bristow RE, Santoso JT, et al. Am J Obstet Gynecol. 2014 Jul; 211(1):65.e1-65.e11. doi: 10.1016/j.ajog.2014.02.010

Objective

The study compared OVA1 head-to-head or in combination with ultrasound (US) or CT scan to predict the likelihood of ovarian malignancy before surgery. 1024 evaluable patients from previously performed, prospective national trials, that included 44 clinical sites from the years 2007 through 2012, were retrospectively analyzed for the following end points:

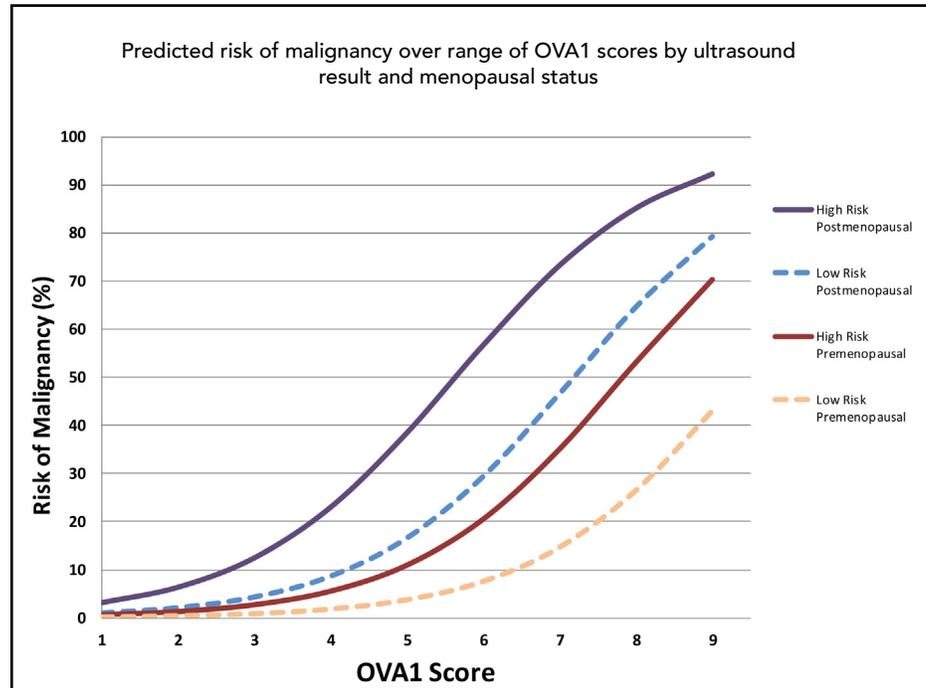
Sensitivity: The percent of patients with a malignant mass who had a positive test result

Specificity: The percent of patients with a benign mass who had a negative test result

Key Results

- US alone missed 23% (21/91) of ovarian cancers compared to 11% (10/91) by OVA1 as a standalone test; results were similar in comparing CT scan alone and OVA1.
- Adding OVA1 to US reduced ovarian cancer missed to just 2% (2/91)
- Specificity of OVA1 alone was comparable to US (51% vs 55%) in 630 benign patients

n = 721	Ultrasound	OVA1 alone	Ultrasound with OVA1
Malignancy identified	70	81	89
Malignancy not identified	21	10	2



High-risk ultrasound:
Presence of solid tumor or papillary morphologic condition

Low-risk ultrasound:
Unilocular or septate cystic ovarian tumors and no high risk finding

(Ascites and metastatic implants excluded from study)

Conclusion

Imaging, OVA1 score and menopausal status independently affected ovarian risk in women with adnexal mass planned for surgery. The results helped define how US and the OVA1 score work together to identify patients at higher risk of malignancy.