Impact of a Multivariate Index Assay on Referral Patterns for Surgical Management of an Adnexal Mass

Robert E. Bristow, et al. Am J Obstet Gynecol. 2013 Dec; 209(6):581.e1-8. doi: 10.1016/j.ajog.2013.08.009

Overview

The study evaluated the referral pattern and sensitivity of using OVA1 against multiple triage methods to direct adnexal masses to gynecologic oncologists for possible malignancy. 770 intended use patients were enrolled by non-gynecologic oncologists from two related, multi-institutional, prospective trials and analyzed retrospectively.

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

Referral rate: *The percent of patients actually referred or predicted by a positive test result*

Key Results

	CA-125	Clinical assessment	Dearking modified-ACOG guidelines	OVA1 alone
	High risk cutoff: - Premenopausal subjects CA125 >67U/mL - Postmenopausal subjects CA125 >35U/mL	Included physical examination, family history, imaging, and CA125 results, if used	Premenopausal women: - Very elevated CA125 (>67units/mL) - Ascites - Evidence of abdominal or distant metastasis Postmenopausal women - Elevated CA125 (>35 units/mL) - Nodular or fixed pelvic mass - Ascites - Evidence of abdominal or distant metastasis	Stratified as high risk with OVA1 scores ≥5.0 (premenopausal) or ≥4.4 (postmenopausal)
Sensitivity	68% (112/164)	73% (120/164)	79% (130/164)	90% (148/164)

	Actual referral in clinical practice	OVA1 alone
	Any and all available diagnostic triage methods (inclusive of physical exam, imaging and biomarkers, if used) for referral to a gynecologic oncologist for surgical intervention	Stratified as high risk with OVA1 scores ≥5.0 (premenopausal) or ≥4.4 (postmenopausal)
Referral rate	60%	56%

Conclusion

OVA1 was associated with a gynecologic oncologist referral rate (56%) comparable to actual clinical practice (60%) and had higher sensitivity for malignancy than clinical assessment, CA125, and modified-ACOG guidelines.

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:

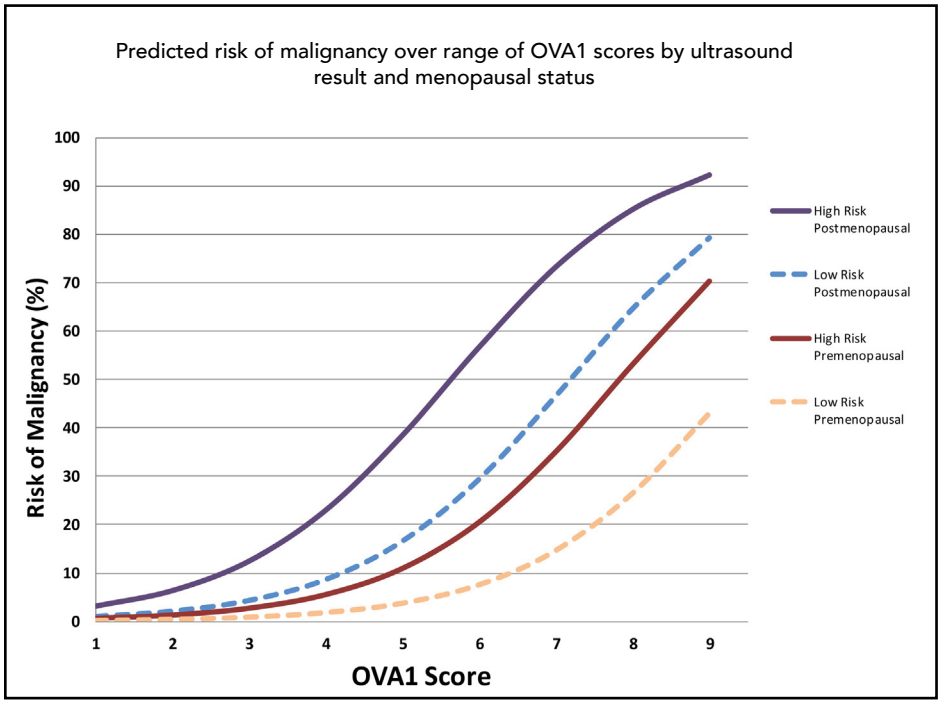
Sensitivity: *The percent of patients with a malignant mass who had a positive test result*

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.

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Cost Effectiveness of a Multivariate Index Assay Compared to Modified ACOG Criteria and CA-125 in the Triage of Women with Adnexal Masses

Forde GK, Hornberger J, Michalopoulos S, et al. Presented at the Annual Meeting of the American College of Medical Quality, March 26, 2015

Overview

The study evaluated the cost effectiveness of OVA1 against modified ACOG (mACOG) referral guidelines and CA-125 testing alone for use in triaging women with adnexal mass to gynecologic oncologists for possible malignancy. Patient data 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 to determine cost effectiveness:

Direct treatment costs: *CMS fee schedule was primarily used to estimate cost of test, CT scan, surgery, staging and chemotherapy*

Quality-adjusted life-year (QALY): *A measure of quality of life that takes into account both the quantity and the quality of life generated by interventions*

Incremental cost-effectiveness ratio (ICER): *Average incremental cost associated with one additional unit of the measure of effect (i.e., QALY) between two possible interventions. The ICER threshold, or indication of cost-effectiveness of one modality versus another, was set at the commonly accepted figure of $50,000/QALY. ICERs below $50,000/QALY indicate comparative cost effectiveness of that modality.*

Key Results

- Use of OVA1 resulted in fewer projected re-operations and pre-treatment CT scans versus CA 125-II or mACOG
- OVA1 increased the quality adjusted life years (QALY) of the patient cohort
- OVA1 was shown to be cost effective versus mACOG ($35,094/QALY) or CA-125 ($12,189/QALY) as both were below the $50,000/QALY threshold
- ICER was most affected by changes to the following parameters:
  - » Sensitivity of OVA1 and mACOG
  - » Percent of ovarian cancer patients not referred to gynecologic oncologist

Conclusion

Use of OVA1 was a more cost-effective triage method for women with adnexal masses than mACOG or CA-125 alone and would increase the percentage of women with ovarian cancer who are referred to gynecologic oncologists, which has been shown to improve clinical outcomes.

	Direct Cost	Δ Cost	QALY	ICER
OVA1	$12,789	-	17.005	-
CA-125	$12,540	$250	16.985	$12,189
Modified ACOG	$12,430	$359	16.995	$35,094
	Threshold to be considered cost-effective			**$50,000**

Note: Testing for BRCA1/2 mutations in women at high risk for ovarian or breast cancer was shown to have an ICER of $36,800/QALY (Li, et al., 2011 CTRC-AACR San Antonio Breast Cancer Symposium). Vanderlaan, et al. showed that use of Oncotype Dx in node-positive, early-stage breast cancer patients had a cost effectiveness ratio of $15,578/QALY (Vanderlaan, et al., 2011 AJMC).