

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

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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.