



A real-world comparison of the clinical and economic utility of OVA1 and CA125 in assessing ovarian tumor malignancy risk

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Aim: This largest-of-its-kind study evaluated the clinical utility of CA125 and OVA1, commonly used as ovarian tumor markers for assessing the risk of malignancy. The research focused on the ability and utility of these tests to reliably predict patients at low risk for ovarian cancer. Clinical utility endpoints were 12-month maintenance of benign mass status, reduction in gynecologic oncologist referral, avoidable surgical intervention and associated cost savings. **Materials & methods:** This was a multicenter retrospective review of data from electronic medical records and administrative claims databases. Patients receiving a CA125 or OVA1 test between October 2018 and September 2020 were identified and followed for 12 months using site-specific electronic medical records to assess tumor status and utilization outcomes. Propensity score adjustment was used to control for confounding variables. Payer allowed amounts from Merative MarketScan Research Databases were used to estimate 12-month episode-of-care costs per patient, including surgery and other interventions. **Results:** Among 290 low-risk OVA1 patients, 99.0% remained benign for 12 months compared with 97.2% of 181 low-risk CA125 patients. The OVA1 cohort exhibited 75% lower odds of surgical intervention in the overall sample of patients (Adjusted OR: 0.251, $p \leq 0.0001$), and 63% lower odds of gynecologic oncologist utilization among premenopausal women (Adjusted OR: 0.37, $p = 0.0390$) versus CA125. OVA1 demonstrated significant savings in surgical interventions (\$2486, $p \leq 0.0001$) and total episode-of-care costs (\$2621, $p \leq 0.0001$) versus CA125. **Conclusion:** This study underscores the utility of a reliably predictive multivariate assay for assessing ovarian cancer risk. For patients assessed at low risk of ovarian tumor malignancy, OVA1 is associated with a significant reduction in avoidable surgeries and substantial cost savings per patient. OVA1 is also associated with a significant reduction in subspecialty referrals for low-risk premenopausal patients.

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Ovarian cancer is the fifth highest cause of cancer related deaths among women [1,2]. An estimated 5–10% of women will develop an adnexal mass during their lifetime [3]. Surgical intervention is a common treatment option, yet studies have shown that only 10% of the 200,000 patients in the USA who undergo surgery for an adnexal mass annually are found to have ovarian cancer [4]. Of those diagnosed with cancer the estimated 5-year survival rate is only 49% [5]. As a result of the low prevalence but high mortality risk, it is important for gynecologists to have access to and utilize safe tests with high negative predictive value (NPV) to accurately differentiate adnexal masses at low risk of being malignant, allowing them to determine the best care pathway and avoid unnecessary treatment.

There are no US FDA-approved tests to detect and diagnose ovarian cancer. First identified in 1981, the serum cancer antigen 125 (CA125) is a single-protein biomarker that has been regularly used by clinicians to assess ovarian masses for malignancy, although it is FDA approved only for monitoring the recurrence of ovarian cancer after treatment. The CA125 test, while useful for assessing more progressive stages of disease, has not been shown to be effective at identifying earlier disease due to the test's low sensitivity, especially among premenopausal women [6,7]. Cleared by the FDA for clinical use in 2009, the multivariate index assay (OVA1[®]), developed by Aspira Women's Health, Inc. (TX, USA), is used to help physicians assess if an ovarian mass is malignant prior to surgery [6,7]. The OVA1 test evaluates five protein biomarkers (Apolipoprotein A1, Beta 2 microglobulin, CA125, Prealbumin and Transferrin) to determine ovarian cancer risk [8]. OVA1 test results indicate low, high or intermediate risk. The OVA1 test has been shown to detect cancer more accurately among women of varying ages and racial/ethnic backgrounds compared with CA125 [7,9]. When compared with CA125, the OVA1 test consistently performed better when comparing sensitivity (OVA1: 95–96%; CA125: 70–79%) and NPV (OVA1: 95–98%; CA125: 86–94%) for assessing the risk of ovarian mass malignancy when OVA1 was accompanied by clinical assessment [7,10,11]. Both tests are used in conjunction with diagnostic imaging and independent clinical evaluation.

Patients deemed at low-risk for ovarian cancer malignancy by valid and reliable biomarker tests can effectively avoid healthcare interventions typically reserved for high risk and/or malignant cases, including specialty physician referrals, surgery and chemotherapy [12]. Reduction in these services among low-risk patients not only results in reduced utilization of healthcare services, but also shields patients from the disutility of interventions and aids in the conservation of costs. Past studies have shown that the use of cancer risk-assessment tests, can be effective at mitigating procedures by up to 60% for other cancers [13].

Additional research is needed to better understand the clinical utility of OVA1 and CA125 used to assess adnexal mass malignancy risk. The purpose of this study was to evaluate these risk-assessment tests and their impact on the patient's course of treatment and related resource consumption, specifically regarding specialty physician referrals, surgical interventions and associated episode-of-care (EOC) costs within each cohort. A better understanding of clinical utility defined in these terms and based on real-world outcomes can assist decision makers to appropriately deploy such tests.

Materials & methods

This study was a multisite, retrospective analysis of female patients receiving a CA125 or OVA1 index test between October 2018 and September 2020 using clinical data extracted from electronic medical records (EMRs). Subjects were followed for 12 months after the index test for key clinical and economic end points.

Inclusion/exclusion criteria

Women ≥ 18 years of age and who received either an OVA1 or CA125 risk-assessment tests were included in the study. Additionally, the study was limited to patients diagnosed with an adnexal mass that received imaging/transvaginal ultrasound in conjunction with physician evaluation. Patients were excluded if they visited a gynecologic oncologist in the 6 months prior to their index OVA1 or CA125 diagnostic test, as risk assessment had already been performed by the oncologic specialist without reliance on OVA1 test results.

Study cohorts

Patients were divided into two cohorts based on whether they received OVA1 or CA125 as their index test. Within each cohort, patients were evaluated for risk of malignancy (high risk vs low risk) using a combination of their menopausal status (pre- or postmenopausal) and their test score, as outlined in FDA guidelines and test instructions for use. In the OVA1 cohort, a test score less than 5.0 was considered low risk for malignancy among premenopausal women and a test score less than 4.4 was considered low risk for postmenopausal women [14]. In the CA125 cohort, premenopausal women with scores less than 67 and postmenopausal women with scores less than 35 were considered low risk for malignancy [15,16].

Data collection

Primary clinical end points included sustained maintenance of benign ovarian mass status, rate of surgery and gynecologic oncologist consultation in the 12 months following the index test among patients at low risk of having a malignant mass. Post index test EOC costs at the patient level were also measured.

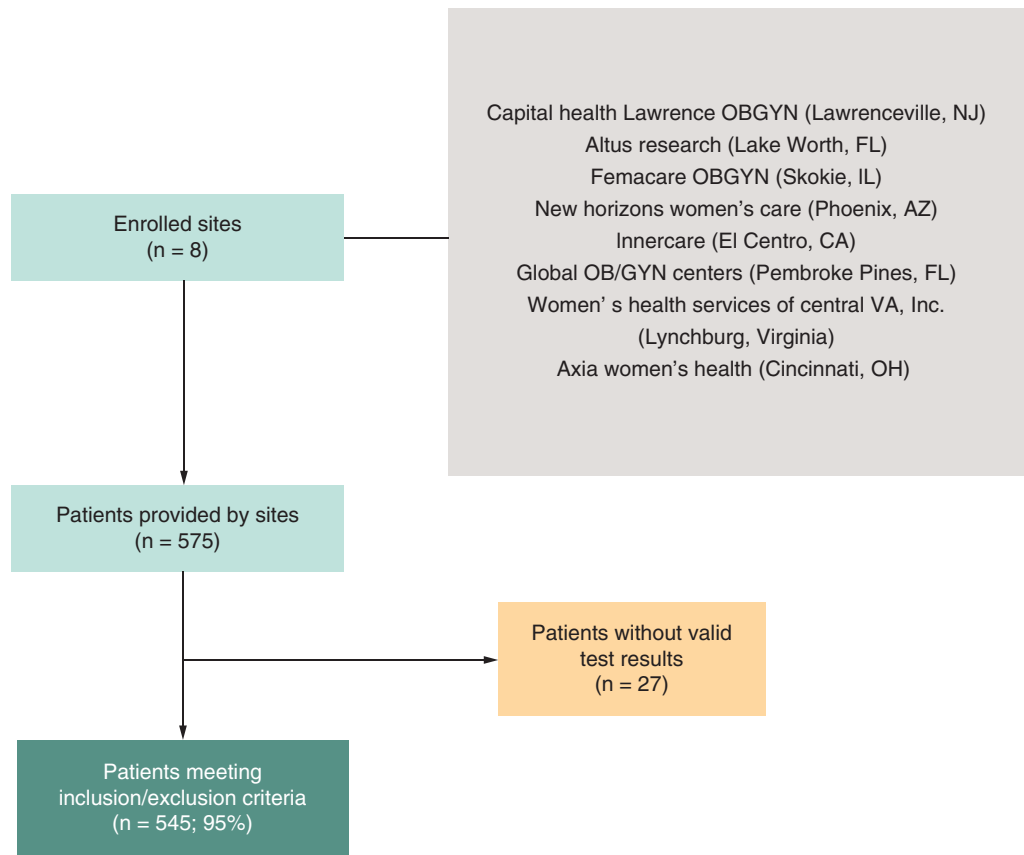


Figure 1. Study patient flow chart and site description.

Clinical end points were identified via International Classification of Diseases (ICD-10) codes, current procedural terminology codes, as well as through patient chart review. The full coding scheme used in this study is listed in [Appendix Table 1](#).

Clinical data were collected from eight sites across the USA, representing a geographically diverse sample of patients tested with OVA1 or CA125. Each site provided similar numbers of OVA1 and CA125 cases, with one site providing only OVA1 records for analysis due to widespread physician adoption of that test. A total of 579 records were received including 384 OVA1 cases and 195 CA125 cases. A flow diagram of the site selection scheme is present in [Figure 1](#).

The case report form (CRF) for collecting clinical data from the EMRs was completed either by the site's research team or the study administrator (Baker Tilly US, LLP, IL, USA). In the latter scenario, certified medical coding professionals completed the CRFs. In both cases, a rigorous quality control process was conducted by the study administrator to ensure consistent and accurate CRF completion.

Healthcare costs, payer allowed amounts which include payer and patient responsibility, were evaluated subsequent to index testing for the following services: inpatient hospital services, outpatient hospital services, emergency department services and physician office services. EOC costs were also calculated as the sum of costs associated with the previously identified clinical services. Cost data were collected via retrospective review of Merative MarketScan Research Databases (Merative, Ann Arbor, MI, USA), a commercial administrative claims dataset, based on the DRG or current procedural terminology codes associated with the post index service received. This dataset was selected for its strength as a multipayer, nationally representative population.

Statistical analysis

Demographic categorical data were compared between groups using a Pearson's Chi-squared or Fisher's exact test. Independent sample *t*-tests were used to compare surgery cost across cohorts. Utilization outcome events

were analyzed with Pearson's Chi-squared and Fisher's exact tests when appropriate. The threshold for statistical significance was set *a priori* at $\alpha < 0.05$.

Propensity score adjustment was used to balance baseline characteristics across the study cohorts. Propensity scores were generated based on a combination of patient demographic (age, menopausal status) and comorbidity characteristics (hypertension, obesity, morbid obesity and diabetes). Unadjusted standardized differences of categorical variables were calculated using the Mahalanobis distance estimation methodology. Standardized differences of continuous variables were calculated using general linear models. The propensity scores were then used in a multivariate regression model to generate adjusted clinical utility outcomes for both binary and continuous variables. Standardized differences of continuous variables were calculated using general linear models. Statistical analyses were performed using SAS Enterprise Guide (v7.1, SAS Institute Inc., NC, USA).

Ethical review

The study received an expedited review and approval by the full board at the WIRB-Copernicus Group (WCG) Institutional Review Board (IRB). Per the WCG IRB approval, patient consent was waived as the research involved no more than minimal risk, could not be practically carried out without the waiver and did not adversely affect the rights and/or welfare of the participants.

Results

A total of 545 patient records were collected: 351 patients in the OVA1 cohort and 194 patients in the CA125 cohort. Patients identified by OVA1 or CA125 as high-risk were excluded from analysis due to the small number of records represented, particularly in the CA-125 cohort (61 high-risk OVA1 and 13 high-risk CA125 patients). Accordingly, the analysis focused on low-risk OVA1 and CA125 patient populations. Based on the index test result, 290 OVA1 patients were deemed low risk compared with 181 CA125 patients. Unadjusted low-risk patient baseline characteristics and comorbidities are presented in [Table 1](#). Before adjustment, the OVA1 cohort was significantly younger (49.18 vs 53.4, $p = 0.0025$), had significantly lower rates of obesity (19.0 vs 28.2%, $p = 0.0233$) and significantly more premenopausal (63.5 vs 43.7%, $p \leq 0.0001$) than the CA125 cohort. The propensity score adjustment model was successful in balancing the differences between the two cohorts ([Table 1](#)).

Maintenance of benign ovarian mass status

Benign mass status was evaluated among the low-risk OVA1 and CA125 cohorts to assess the accuracy of each in predicting risk of malignancy ([Table 2](#)). Among the 290 patients in the low-risk OVA1 cohort, 99.0% of patients remained benign during the entire follow-up period compared with 97.2% of the 181 low-risk CA125 cohort patients, although this observed difference did not achieve statistical significance ($p = 0.2700$). The results did not change appreciably at the subgroup level of premenopausal and postmenopausal.

Post index test surgical events

Following the index test, surgical procedure events were captured for each patient ([Table 2](#)). The OVA1 cohort underwent 28.2% fewer surgical procedures (15.5 vs 43.7%, $p \leq 0.0001$) and exhibited 75% lower odds of having a surgical procedure when compared with the low-risk CA125 cohort (adjusted OR: 0.25; 95% CI: 0.16–0.39; $p \leq 0.0001$). The results did not change substantially at the subgroup level of premenopausal and postmenopausal.

Gynecologic oncology service utilization

The low-risk OVA1 cohort had 34% reduced odds of utilizing the services of gynecologic oncologists versus the low-risk CA125 cohort (adjusted OR: 0.67; 95% CI: 0.34–1.30; $p = 0.2301$). While this result did not meet statistical significance in the aggregate analysis, OVA1 was associated with a significant 63% reduction in utilization of gynecologic oncologists among premenopausal patients (adjusted OR: 0.37; 95% CI: 0.14–0.95; $p = 0.0390$) ([Table 2](#)).

Post index EOC cost differences

Unadjusted and adjusted total post index EOC costs for low-risk OVA1 and CA125 cohorts are reported in [Table 3](#). After adjustment, the low-risk OVA1 cohort reported total per patient EOC costs of \$7240 compared with \$9861 in the low-risk CA125 cohort; $p \leq 0.0001$. Nearly all of the cost-savings in the low-risk OVA1 cohort (~95%) was

Table 1. Unadjusted patient baseline characteristics.

	OVA1 n = 290	CA125 n = 181	Cohort comparison			Propensity score adjustment
Characteristic	Mean ± SD or % (n)	Mean ± SD or % (n)	Difference	p-value	Standardized difference (OVA1-CA125) [‡]	p-value
Patient demographics						
Age (years) [†]	49.2 ± 15.4	53.4 ± 14.0	-4.2	0.0025	-0.307498	0.8582
Race [§]						
White/Caucasian	32.1% (93)	59.1% (107)	-27.0%	<0.0001	-	-
Black African–American	4.1% (12)	5.0% (9)	-0.9%		-	-
Asian	1.0% (3)	3.3% (6)	-2.3%		-	-
Other	0.0% (0)	0.0% (0)	-		-	-
Unknown/not reported	62.8% (182)	32.4% (59)	30.4%		-	-
Ethnicity						
Hispanic	16.2% (47)	14.9% (27)	1.3%	0.7949	-	-
Region [¶]						
Midwest	7.6% (22)	46.4% (84)	-38.8%	<0.0001	-	-
Northeast	18.6% (54)	5.0% (9)	13.6%		-	-
South	70.0% (203)	40.3% (73)	29.7%		-	-
West	3.8% (11)	8.3% (15)	-4.5%		-	-
Patient body characteristics						
Height (cm)	161.9 ± 8.2	163.4 ± 21.9	-1.5	0.3010	-	-
Weight (kg)	75.7 ± 18.5	75.3 ± 18.9	0.4	0.8415	-	-
Patient menopausal status						
Premenopausal [†]	63.5% (184)	43.7% (79)	19.8%	<0.0001	0.405101	0.4566
Patient comorbidities						
Hypertension [†]	19.7% (57)	27.6% (50)	-7.9%	0.0544	-0.188397	0.9693
Obesity [†]	19.0% (55)	28.2% (51)	-9.2%	0.0233	-0.218310	0.9522
Morbid obesity [†]	5.2% (15)	7.2% (13)	-2.0%	0.4244	-0.083560	0.9770
Diabetes [†]	4.5% (13)	6.6% (12)	-2.1%	0.3983	-0.093831	0.9667
Index test score						
Index test score	3.7	13.8	-	<0.0001	-	-

[†] Items included as covariate in propensity score adjustment.

[‡] Standardized difference of continuous variables were calculated using general linear models. Unadjusted standardized mean difference of categorical values were calculated using the Mahalanobis distance estimation methodology.

[§] Race was not included in the propensity scores due to a large percent reported as ‘Unknown/not reported’.

[¶] Region was not included in the propensity scores since the results of the test will not be impacted based on patient location.

a result of significantly lower surgical procedure costs. The low-risk OVA1 cohort demonstrated \$2486 in surgical procedure costs savings per patient versus the low-risk CA125 cohort (\$1420 vs \$3906, $p \leq 0.0001$). The results did not change substantially at the subgroup level of premenopausal and postmenopausal.

Discussion

For patients assessed at low risk of ovarian tumor malignancy, this study suggests that use of the OVA1 test is associated with a significant reduction in surgical procedures and related EOC costs per patient in comparison to patients who received a CA125 test. Due to the limited sample of high-risk patients (OVA1 = 61, CA125 = 13), this group was not included in the analysis. As observed in this study, the impact of early risk assessment is substantial and includes a combination of clinical and economic impacts.

In the present study, significant reductions were observed in surgical procedure utilization and surgical procedure costs that may be attributed to more effective management of the patient's treatment plan following the use of a reliably predictive risk-assessment test. Prior evidence supports the conclusion that use of valid and reliable NPV tests enables patients at low risk of malignancy to maintain standard treatment services with their gynecologists, while also avoiding unnecessary and costly surgical interventions [17]. Studies have shown the use of tests assessing malignancy risk can result in the avoidance of up to 60% of unnecessary procedures; however, the focus was not on ovarian cancer [13]. The possibility of further surgery reduction as well as favorable outcomes through reliable

Table 2. Clinical utility outcomes.

	Unadjusted outcomes				Adjusted outcomes	
	OVA1 patients % (n; 95% CI)	CA125 patients % (n; 95% CI)	Cohort comparison		Odds ratio (95% CI)	p-value
All patients	290	181	% Δ	p-value	-	-
12-month maintenance of benign mass status	99.0% (287; 97.8%, 100.0%)	97.2% (176; 94.8%, 99.7%)	1.8%	0.2700	2.64 (0.60, 11.57)	0.1982
Surgical procedures	15.5% (45; 11.3%, 19.7%)	43.7% (79; 36.4%, 50.9%)	-28.2%	<0.0001	0.25 (0.16, 0.39)	<0.0001
Gynecologic oncologist encounters [†]	6.9% (20; 4.0%, 9.8%)	11.0% (20; 6.4%, 15.7%)	-4.1%	0.1278	0.67 (0.34, 1.30)	0.2376
Premenopausal patients	184	79	-	-	-	-
12-month maintenance of benign mass status	99.5% (183; 98.4%, 100.0%)	96.2% (76; 91.9%, 100.0%)	3.3%	0.0824	6.95 (0.71, 68.14)	0.0961
Surgical procedures	14.7% (27; 9.5%, 19.8%)	43.0% (34; 31.9%, 54.2%)	-28.3%	<0.0001	0.23 (0.13, 0.42)	<0.0001
Gynecologic oncologist encounters [†]	4.9% (9; 1.8%, 8.0%)	12.7% (10; 5.2%, 20.2%)	-7.8%	0.0362	0.37 (0.14, 0.95)	0.0390
Postmenopausal patients	106	102	-	-	-	-
12-month maintenance of benign mass status	98.1% (104; 95.5%, 100.0%)	98.0% (100; 95.3%, 100.0%)	0.1%	1.0000	1.05 (0.14, 7.71)	0.9609
Surgical procedures	17.0% (18; 9.7%, 24.3%)	44.1% (45; 34.3%, 53.9%)	-27.1%	<0.0001	0.27 (0.14, 0.51)	<0.0001
Gynecologic oncologist encounters [†]	10.4% (11; 4.5%, 16.3%)	9.8% (10; 3.9%, 15.7%)	0.6%	1.0000	1.14 (0.46, 2.84)	0.7823

[†] Gynecologic oncologist encounters is the percentage of patients that had at least one encounter with a gynecologic oncologist.

Table 3. Post index total healthcare costs for patient cohorts.

	Unadjusted outcomes					Adjusted outcomes				
	OVA1 patients	CA-125 patients	Cohort comparison			OVA1 patients	CA-125 patients	Cohort comparison		
Volume	290	181	\$ Δ	% Δ	p-value	290	181	\$ Δ	% Δ	p-value
Nonsurgical inpatient	\$1828	\$1651	\$177	11%	0.7633	\$1803	\$1690	\$114	7%	0.4628
Nonsurgical outpatient	\$1993	\$2285	-\$292	-13%	0.4378	\$2018	\$2244	-\$226	-10%	0.0423
Physician office	\$1995	\$2001	-\$6	0%	0.7371	\$1990	\$2008	-\$17	-1%	0.0166
Emergency department	\$8	\$13	-\$5	-37%	0.4575	\$9	\$13	-\$4	-32%	<0.0001
Surgical procedure	\$1382	\$3967	-\$2585	-65%	<0.0001	\$1420	\$3906	-\$2486	-64%	<0.0001
Total per patient cost [†]	\$7205	\$9916	-\$2711	-27%	0.0053	\$7240	\$9861	-\$2621	-27%	<0.0001
Total aggregate cost	\$2,089,540	\$1,794,818	\$294,722	16%	-	\$2,099,595	\$1,784,763	\$314,832	18%	-

[†] Total per patient cost is the average cost per patient per cohort; calculated as the total sum cohort aggregate cost divided by the number of patients in each cohort.

predictive testing is one that payers should closely consider. The present study underscores these impacts among low-risk patients, with the low-risk OVA1 cohort exhibiting significantly lower odds of progressing to surgery than the low risk CA125 cohort following their index diagnostic test (Table 2). Moreover, the present study observed a significant reduction in gynecologic oncology services for the premenopausal OVA1 subgroup (Table 2). This may be attributed to premenopausal patients with conditions such as endometriosis or fibroids that may present falsely elevated CA125 levels which can be accurately measured with OVA1.

The use of reliably predictive tests not only aids in the detection and treatment of ovarian cancer while mitigates healthcare utilization and costs, it also likely improves patient quality of life through the avoidance of surgery and its complications, including anxiety and fear one may experience due to surgery. The low-risk OVA1 cohort reported significantly lower adjusted total EOC costs per patient when compared with the low-risk CA125 cohort, with the majority of savings being from a significant reduction in surgical procedures. These economic trends highlight the considerable cost savings associated with reliable predictive tests among the low-risk OVA1 cohort due to moderated surgical interventions.

This study has several notable strengths. First, this is the largest study to date of the clinical utility of OVA1 in patients with ovarian tumors assessed as low risk of malignancy. Another key strength is the underlying source of the data, which was EMR information secured directly from the participating clinical sites. Therefore, many of the limitations of claims data such as test results availability, reliance on medical coding to capture all relevant activity and incomplete comorbidity profiles, were allayed. Additionally, the geographic heterogeneity of cases analyzed provides a degree of generalizability worth noting. While there was variance in the volume of patient records contributed to each cohort across the enrolled sites, the current study was still able to capture geographic diversity from the contributing facilities, as well as the types of practices included, such as private practices, physician medical groups and a nonprofit clinic. The variance in cohort volumes also underscores the difference of indication of use for OVA1 among our study population, as well as the variance in how gynecologists utilize OVA1 when referring patients to oncologic specialists in real-world situations. The larger number of OVA1 patients demonstrates that clinicians are using OVA1 as intended versus CA125. Length of follow-up was another strength of the study, as patients were followed retrospectively for 12 months post index test to capture downstream healthcare utilization and its associated costs. Finally, our analysis did not attempt to manage outliers or seek sites with known care protocols, thereby allowing the study to capture real-world trends that were not governed by any randomized control trial restrictions or over-reaching statistical approaches.

Along with these strengths, there are limitations inherent to retrospective chart reviews. Because of the reliance on medical records, data quality is dependent upon accurate documentation and the ability of the medical records reviewer to understand the gathered information. As is true of all ‘real world’ studies, it is not possible to fully control for exogenous factors that could influence the results of the study, such as determination of eligibility to receive an ovarian cancer diagnostic test and which test (OVA1 or CA125) they should receive. Despite both tests using biomarkers to determine the likelihood of ovarian cancer, there may be other clinical factors physicians rely upon to determine which test patients receive. Additionally, OVA1 is not widely covered across all commercial plans, limiting which physicians can order the test and ultimately which patients can receive it. The authors assessed the impact of the volume imbalance and potential data skewness and determined that a propensity score adjustment methodology was most appropriate to both leverage the considerable treatment cohort volume and maintain the comparator cohort volume. Moreover, the low prevalence of high-risk cases led us to postpone analysis of this subgroup until adequately powered samples can be obtained. Additionally, the study’s utilization and economic outcomes were captured from events occurring within the enrolled site’s EMR, which may have excluded a nominal number of ‘out-of-network’ events. Lastly, the surgery metrics did not capture utilization of laparotomies, which the participating sites confirmed was not the standard-of-care and is rarely deployed based on the presence of the preferred minimally invasive surgical approach.

Conclusion

Randomized controlled clinical trials are traditionally relied upon to assess the utility of new drugs and devices but are of questionable external validity regarding generalizability and transferability of results [18]. This study utilized RWE drawn from patient EMRs combined with claims data and underscores the utility of highly accurate NPV multivariate assays for assessing risk of ovarian cancer. This study has demonstrated that women who are tested with OVA1, and whose scores are within the low-risk range, experienced significantly fewer surgical procedures and compared with the CA125 cohort, with a significant reduction in gynecological oncologist referrals for the OVA1 premenopausal group. The noted reduction in surgeries and referrals anchored the significant EOC cost savings associated with the use of OVA1.

Opportunities for future research include using cost-utility modeling to estimate the long-term impact of utilizing biomarker assays on ovarian tumor treatment costs and quality of life.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: <https://bpl-prod.literatumonline.com/doi/10.57264/cer-2023-0025>

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Ethical conduct of research

The study received an expedited review and approval by the full board at the WIRB-Copernicus Group (WCG) IRB. Per the WCG IRB approval, patient consent was waived as the research involved no more than minimal risk, could not be practically carried out without the waiver, and did not adversely affect the rights and/or welfare of the participants

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Summary points

- Ovarian cancer is the fifth highest cause of cancer related deaths among women.
- While only 10% of women who undergo surgery for an adnexal mass are found to have ovarian cancer, accurate diagnosis is critical to long term survival.
- This retrospective real-world study evaluated the clinical and economic utility of (CA125 and OVA1), two blood tests commonly used as ovarian tumor markers for assessing the risk of malignancy.
- Clinical data for the study were collected from electronic medical records at multiple practice sites in the US and supplemented with cost data garnered from the Merative MarketScan Research Database of commercial insurance claims.
- After application of inclusion/exclusion criteria, the total sample comprised 545 patients (351 patients in the OVA1 cohort and 194 patients in the CA125 cohort), the overwhelming majority of which were classified as low risk of malignancy.
- The OVA1 cohort exhibited 75% lower odds of surgical intervention (adjusted OR: 0.25; $p \leq 0.0001$) and 34% lower odds of gynecologic oncologist utilization (adjusted OR: 0.67; $p = 0.2376$) versus CA125. Moreover, OVA1 yielded significant savings in surgical interventions (\$2486, $p \leq 0.0001$) and total EOC costs (\$2621, $p < 0.0001$) versus CA125.
- The study findings suggest that OVA1 is associated with significant reduction in avoidable surgeries overall and subspecialty referrals for premenopausal patients, as well as substantial cost savings per patient.

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