

CA125 glycovariant assays improve the accuracy of ovarian cancer detection

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BACKGROUND

The lack of accurate diagnostic blood tests for ovarian cancer leads to delayed diagnosis and compromised clinical outcome. The most commonly used biomarker CA125 is not specific for ovarian cancer. As the only definitive way of confirming ovarian cancer is surgery, new diagnostic tools are urgently needed to better discriminate between benign and malignant processes preoperatively.

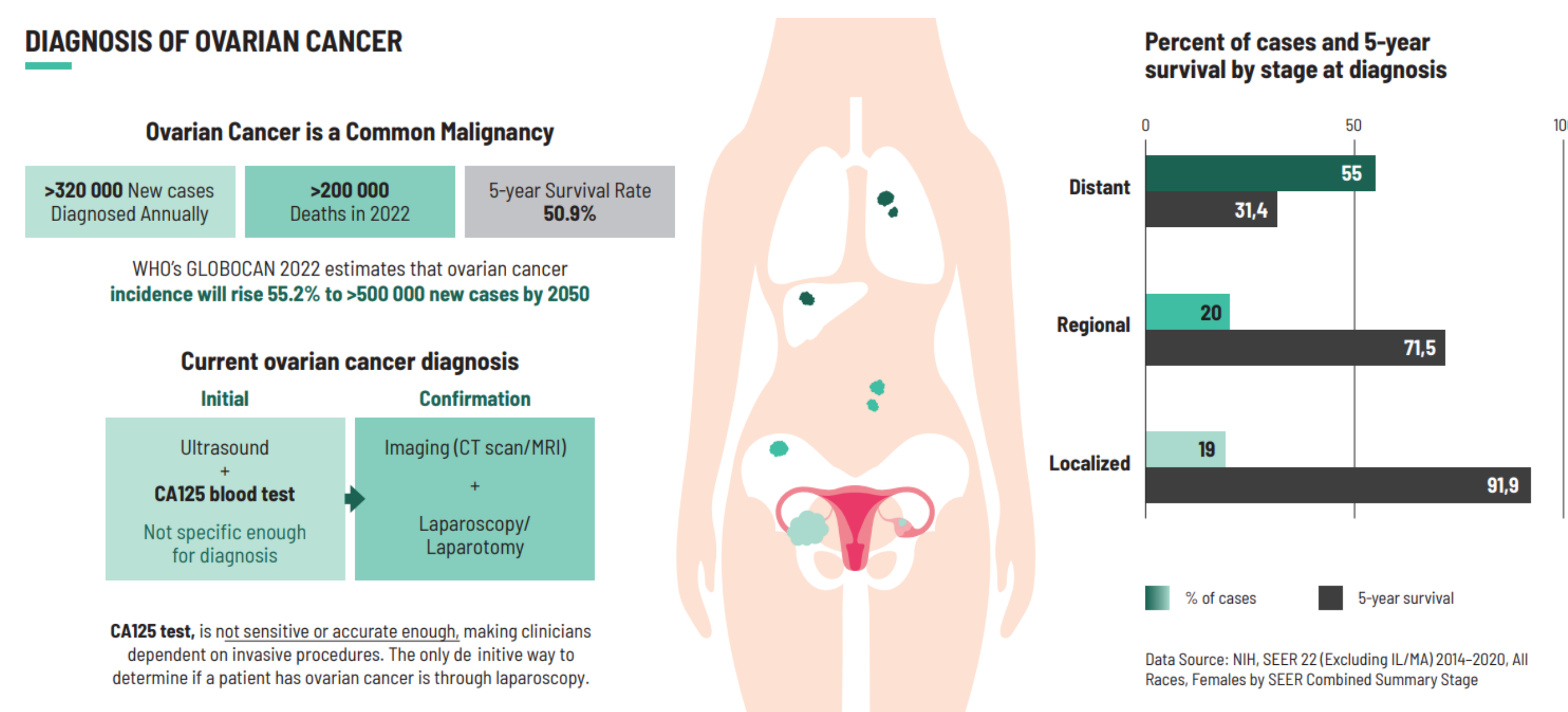


Figure 1. Ovarian cancer is the deadliest gynecological cancer. The 5-year survival rate of advanced ovarian cancer is only 31%, whereas the survival of early-stage disease is over 90%. Thus, the early detection of ovarian masses is an urgent clinical challenge, and resolving it is key to achieving satisfactory oncological outcomes.

ASSAY PRINCIPLE

GLYVAR™ Ovarian assay detects cancer-specific glycosylation on the surface of CA125 protein core. The assay consists of two separate tests: Ovarian I and II. They have different binders coated on the nanoparticles and they detect separate cancer-specific glycovariants for optimal accuracy of ovarian cancer detection.

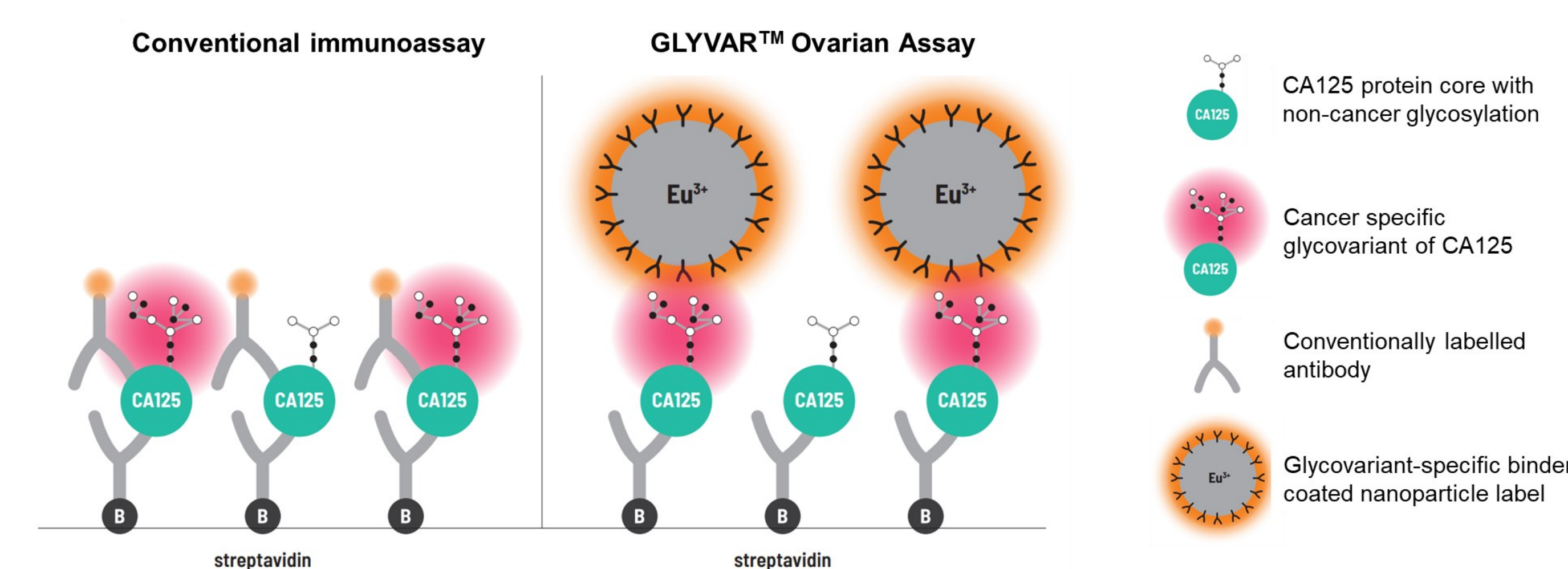


Figure 2. Principle of the GLYVAR™ Ovarian assay. While the conventional CA125 immunoassay (left) detects the CA125 protein core, the GLYVAR Ovarian assay binds the CA125 protein but detects cancer-specific glycovariants on the surface of the CA125 protein core..

RESULTS

Serum samples of 184 women with epithelial ovarian cancer (EOC), 127 benign ovarian tumors, and 115 unaffected controls were measured using GLYVAR™ Ovarian I and II assays (Unio^{gen}) and the conventional CA125 protein assay (Fujirebio).

The main results are:

- Improved accuracy for EOC.** Patients with moderately elevated CA125 concentration at diagnosis are diagnostically challenging. The GLYVAR Ovarian assays showed 2.5 times higher sensitivity (85% vs. 33% with CA125) at 94% specificity. CA125 glycovariants corrected 82% of false positive results given by the conventional CA125 assay.
- More sensitive early-stage detection:** The CA125 glycovariant assays detected 71% of early-stage high-grade serous carcinomas, which is the deadliest type of ovarian cancer, with very high 99% specificity. CA125 had a sensitivity of only 43% which means an 65% increase in the detection rate by the glycovariant assays.
- Full cohort:** The two glycovariant assays differentiated benign and malignant ovarian masses with 88% sensitivity at 99% specificity, while CA125 showed 73% sensitivity.

CONCLUSIONS

The study presents the clinical performance of GLYVAR Ovarian I and II assays in ovarian cancer diagnostics. The results show that the simple and accessible blood test detecting cancer-specific CA-125 glycovariants has remarkable potential to improve detection of ovarian cancer without costly equipment and data analysis resources. The performance improvement was especially prominent with early-stage detection of high-grade serous carcinomas potentially improving the survival possibilities of the patients. The high accuracy of GLYVAR Ovarian test generated significantly less false positives, which could lower the anxiety of patients, while preventing unnecessary invasive and expensive procedures. The test is currently available for research use.

ACKNOWLEDGEMENTS

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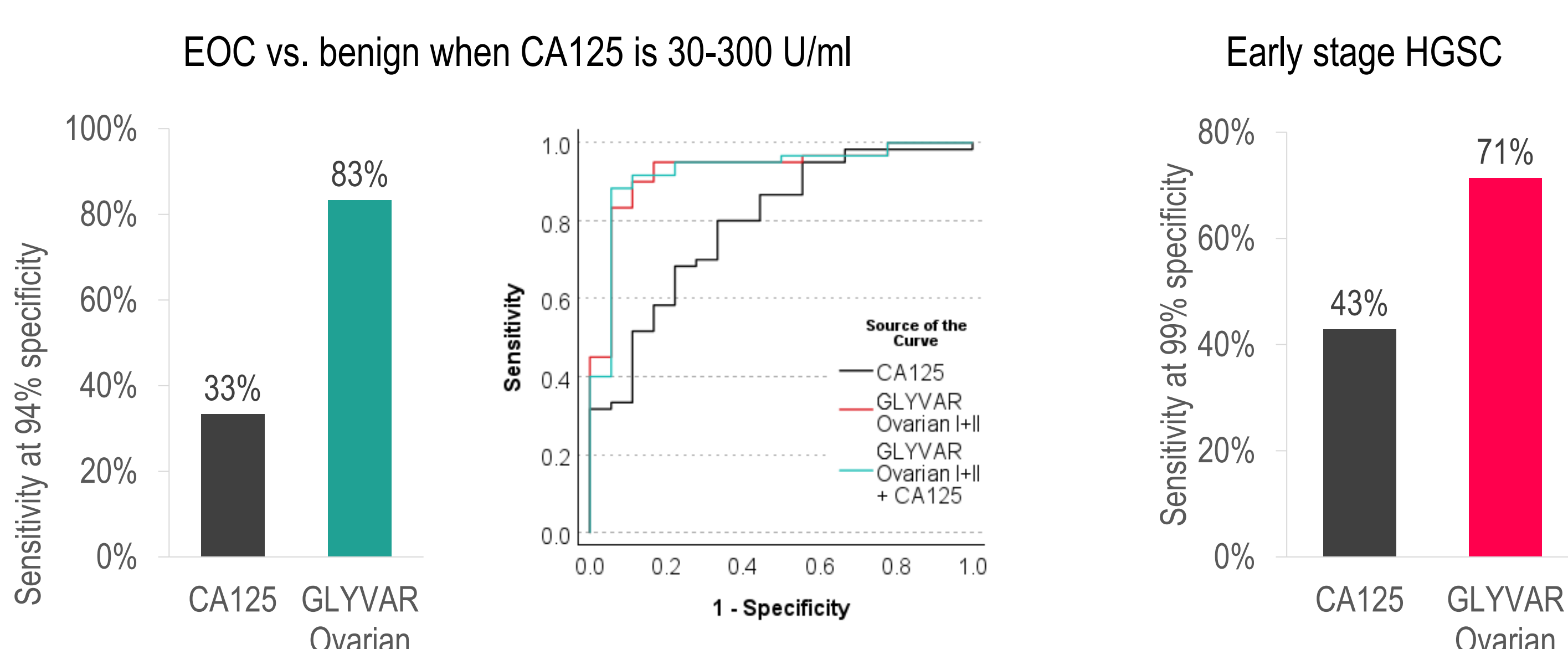


Figure 3. Clinical performance of CA125 glycovariant tests.

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