An Innovative Evidence-Based Laboratory Medicine (EBLM) Test to Help Doctors in the Screening of Ovarian Cancer

Congress

ESMO Gynaecological Cancers Congress 2024, Florence, Italy, from 20 to 22 June 2024

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Background

Ovarian ranks seventh in women's cancers and eighth in female cancer-related deaths. Despite its low incidence, its impact is substantial due to late detection and limited treatment options. Named the 'silent killer' for its vague symptoms, it often leads to delayed diagnosis and metastasis. Hence, early detection remains challenging.

Thus, we present a novel non-invasive test for ovarian cancer early detection. This diagnostic tool aims to accurately detect ovarian cancer, even in early stages, before symptoms appear and when treatment is most likely to succeed.

Methods

This novel algorithm is designed specifically around serum and urine biomarkers for ovarian cancer screening. It primarily relies on the tumor markers CA 19.9, CEA, the ROMA score, which incorporates key factors such as age, menopausal status, and serum levels of CA 125 and HE4, and the CA 125/CEA ratio to generate the likelihood of ovarian cancer, distinguishing between mucinous and serous epithelial ovarian cancer.

To assess the estimated accuracy of our test, we conducted an extensive literature review of diagnostic accuracy studies about constituent algorithms, calculations, and combinations of analytes included within it.

Parallel approximations were conducted to optimize overall sensitivity (Se), followed by serial approximations to enhance specificity (Sp), a process performed by our own machine learning (ML) algorithm**.**

Results

We obtained a final sample size (n) of 9,324 individuals and achieved a Se of 0.97 and a Sp of 0.93. Subsequently, we conducted an approximation of the area under the receiver operating characteristic (AUROC) curve, as well as estimations for the positive predictive value (PPV) and the negative predictive value (NPV) based on these results, yielding values of 0.92, 0.93, and 0.97, respectively.

Conclusions

This data suggests that the innovative non-invasive blood and urine-based biomarker algorithm holds promise in providing timely ovarian cancer screening, particularly among individuals aged 40 and above.

We are conducting an extensive parallel study with additional ovarian analytes to increase the Se of the test and offer the physicians a tool with minimum false negatives.