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

Congress

EMUC (European Multidisciplinary Congress on Urological Cancers) 2024, Lisbon, Portugal, from 7 to 10 November 2024

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Introduction & Objectives

Prostate cancer (PCa) is the fourth most common cancer type worldwide and is also the second most common cancer in men, according to the World Cancer Research Fund (WCRF) International.

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

Materials & Methods

This innovative algorithm is designed specifically around serum and urine biomarkers for PCa diagnosis. Its key biomarkers are the free prostate specific antigen (free PSA), the total PSA, the [-2]proPSA (also known as p2PSA), and the human kallikrein 2 (hK2). The algorithm is primary based on the free PSA/total PSA ratio, which is the most commonly used calculation for PCa screening. But it also incorporates other novel scores, such as the prostate health index (phi), a formula developed by Beckman Coulter (Brea, California, U.S.) that combines all 3 PSA forms (total PSA, free PSA, and p2PSA) into a single score that has been shown to better assess the aggressiveness of PCa; the %p2PSA ((p2PSA/free PSA)*100), which is another novel calculation that also evaluates the malignancy of PCa; and the hK2/free PSA ratio, which has recently been evaluated as a promising tool for the early detection of PCa. The algorithm also includes the hepatic enzymes and the total and the direct bilirubin, as well as the serum creatinine and the urine albumin-to-creatinine ratio (ACR), to detect potentially false positives due to liver disease or kidney disease.
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.

Thereafter, we conducted parallel approximations to optimize overall sensitivity, followed by serial approximations to enhance specificity, a process performed by our own machine learning (ML) algorithm**.**

Results

We obtained a final sample size (n) of 4,868 individuals and achieved a sensitivity of 0.91 and a specificity of 0.86. 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 0.91, 0.87, and 0.90, respectively.

Conclusions

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