

An innovative evidence-based laboratory medicine (EBLM) test to help doctors in the basic assessment of the prostate function

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Background-aim

To develop a novel non-invasive, evidence-based laboratory medicine (EBLM) test to assist doctors in assessing the prostate function and to evaluate its accuracy in detecting the main prostate diseases, such as benign prostate hyperplasia (BPH), prostatitis and prostate cancer (PCa).

Materials & Methods

This study is part of a previous one already published at the European Society for Medical Oncology (ESMO) Congress 2024, which is focused on the accuracy evaluation of a novel non-invasive test for Multi-Cancer Early Detection (MCED). To develop the algorithm, several combinations of analytes were analyzed to identify the most significant groupings related to the prostate function. The algorithm's efficiency was then enhanced using serial and parallel approximation techniques. Its performance was trained with a dataset of 2,160 patients. The validation of the algorithmic test was performed through a randomized controlled trial (RCT) with a sample size of 152 patients. Their blood samples were tested by Laboratorio Echevarne (Spain), using their immunoassay techniques.

Results

For the RCT, the sensitivity achieved was 1.00 and the specificity was 1.00. Additionally, the area under the receiver operating characteristic (AUROC) curve, the positive predictive value (PPV), and the negative predictive value (NPV), were 1.00, 1.00, and 1.00, respectively. This indicates a strong correlation between the algorithm outcomes and the high likelihood of having a prostate disease, including PCa.

Conclusions

This innovative non-invasive blood-based biomarker algorithm holds promise in helping doctors in providing timely and accurate basic assessment of prostate disease and PCa — even in early stages—, as well as reduce medical errors or misdiagnoses. These results advocate further exploration, prompting our intention to conduct a clinical study involving 26,000 participants to enhance our findings and inform clinical practice.