PCA3 Test as an Adjunct in Diagnosis of Prostate Cancer

Introduction and Objective: Early diagnosis of prostate cancer is conventionally done with serum prostate specific antigen (PSA) test and digital rectal examination, but these tests lack specificity. Many men worldwide undergo repeated, sometimes unnecessary prostate biopsies due to suspicious or rising PSA levels. A urine test PCA3 is gaining popularity, predominantly in the field of managing patients with suspicious PSA and previous benign biopsies. In this multi-national study we assessed the performance of the PCA3 urine test in patients who were candidates for prostate biopsies due to high or rising PSA's.
Methods and Patients: The PCA3 scores were determined in urine samples in these men A PCA3 scores of 35 or higher were considered higher probability of cancer. Subsequent biopsy was performed as per current best practice and at the discretion of the urologist in concert with the patient. To retrospectively assess the performance of PCA3, we used multiple logistic regression analysis and ROC curves were constructed to evaluate PCA3 as a prognostic factor compared with PSA and evaluated the influence of PCA3 testing on the decision making.
Results: There were 401 patients who had PCA3 score available. The most common indication was rising or high PSA after previous negative biopsies: in 256 patients (63.8%), followed by the finding of high grade prostatic intraepithelial neoplasia (HGPIN) or atypical small acinar proliferation (ASAP) on previous biopsy – in 101 patients (25.2%). Forty four subjects (11%) did not undergo prostate biopsy prior to PCA3 testing. PCA3 scores were significantly lower in patients without malignancy using a cutoff score of 35 (OR 2.99 (95%CI) (1.42, 6.30), p=0.004). On Receiver Operating Curve analysis PCA3 AUC of 0.722 was significantly greater than PSA (0.4837). Sensitivity and specificity of PCA3 score using the 35 cutoff were 63.6% and 63.0%, respectively. When a cutoff score of 20 was used, the sensitivity and specificity of PCA3 score were 86.4% and 41.3%, respectively. The PCA3 test influenced the clinical course of the patient in 73.5% of cases. The follow-up PSA values in patients who did not perform biopsy after PCA3 testing had, without exception, remained stable or dropped (7.86 vs. 6.22, p=0.003) with follow-up of at least 6 months.
Conclusion: In this multinational study we demonstrate that urine PCA3 score test out-performs PSA in decision making in men facing possibility of repeat prostate biopsy. We recommend that the PCA3 results should be integrated with other relevant data and rather be used in continuous fashion, and not with certain cutoff value.