Utility of PCA3 Urine Assay in Japanese Men Undergoing Prostate Biopsy

Introduction and Objective: To examine the diagnostic performance of PCA3 score for prostate cancer in Japanese men undergoing prostate biopsy.
Materials and Methods: The Japanese, multi-center study included 647 men who underwent prostate biopsy with elevated PSA and/or abnormal digital rectal examination (DRE) from 2009 to 2011. The race was Asian in all case. Urine samples were collected after DRE. PCA3 score was determined using PROGENSA PCA3 assay and correlated with biopsy outcome. The diagnostic accuracy of PCA3 score was compared with serum PSA, prostate volume (PV), PSA density (PSAD), and free/total PSA ratio (f/t PSA). PCA3 score was also correlated with Gleason score, clinical stage, % positive cores, and indolent/significant cancer in men diagnosed with prostate cancer.
Results: The urine samples were successfully analyzed in 633 out of 647 cases (informative rate was 98%). The median PSA was 7.6ng/ml. The biopsy revealed cancer in 264 men (41.7%). PCA3 score in men with prostate cancer was significantly higher than that in men with negative biopsy (median PCA score; 49 vs 18, $p<0.001$). The probability of prostate cancer was 16.0% at a PCA3 score of less than 20 and 60.6% at PCA3 score of 50 or more. Using a cutoff of 35, PCA3 score demonstrated 66.5%, 71.6%, and 69.7% of sensitivity, specificity and diagnostic accuracy, respectively.. The AUCs of PSA, PV, PSAD, and PCA3 score were 0.583, 0.706, 0.712, and 0.748, respectively. The AUC of PCA3 score was significantly higher than that of f/t PSA in men with PSA 4-10ng/ml (0.742 versus 0.647, $p<0.05$). In men with PV >50ml and PCA3 score <20, only 1 (1.7%) out of 56 men had prostate cancer. There were no significant correlations between PCA3 score and Gleason score, clinical stage, % positive cores, and indolent cancer.
Conclusions: PCA3 score was significantly superior to f/T PSA in predicting prostate cancer for men with PSA between 4 to 10 ng/ml. PCA3 score may be useful to reduce the number of unnecessary biopsies especially in men with large prostate.