101 External validation of SelectMDx (v1) in an opportunistic screening cohort in first TRUS-guided biopsy without MRI imaging

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Introduction & Objectives: SelectMDx has been recently proposed as a helpful biomarker in clinical significant prostate cancer (sPCa) detection (grade group ≥2). Our objective is to perform an external validation of the SelectMDx focused in different subcohorts of clinical interest before the 1st biopsy (Bx) within a Spanish opportunistic screening scenario.

Materials & Methods: After a successful testing set, frozen -80º samples from 812 men with PSA≥3ng/ml and/or suspicious DRE and a TRUS guided Bx with a minimum of 10 cores were analyzed without any MRI performed. SelectMDx risk scores for GG≥2 PCa were confronted to PCA3, ERSPC and PBCG (Prostate Biopsy Collaborative Group) risk calculators in a validation process including discrimination, calibration and clinical utility analysis.

Results: Our cohort reported lower risk for sPCa compared to the generation cohort as per PSA, PSAd and % of suspicious DRE, showing 21,1% of GG1 and 16,2% of GG≥2 PCa detection rates. Median SelectMDx score for GG≥2 PCa was 12 (IQR 6-23), showing significant differences related to non PCa+GG1 PCa (5, IQR 1-11) (p<0.001).

a) Men appointed to 1st Bx with PSA 3-10ng/mL; n=515, 71 (13.8%) with sPCa. We obtained an AUC=0,748 (95% CI 0,689-0,807), surpassing PCA3 and ERSPC and PBCG risk calculators. For a cut-off of 3%, we would spare 41% of initial Bx missing 11% of sPCa.

b) Men appointed to 1st Bx; n=547, 14.6% with sPCa; SelectMDx obtained the highest AUC among the tested models, with a value of 0.763 (95% C.I. 0.708-0.819) potentially saving 40% of initial Bx assuming a sPCa non-detection rate of 10% at a cut-off of 3%.

c) Men with with PSA 3-10ng/mL and normal DRE, appointed to 1st Bx; n=462 men, 11.9% with sPCa; SelectMDx obtained again the highest AUC among the 4 models, with a value of 0.736 (95% C.I. 0.668-0.804), potentially saving 37% of initial Bx assuming a sPCa non-detection rate of 11% at the same cut-off.

Conclusions: SelectMDx v1 offered us a moderate discrimination ability, but with valuable clinical utility in clinical scenarios of low expected prevalence of GG>2. In Centers with no easy and reliable availability for MRI before first Bx, it could be a useful tool to avoid around 40% of initial Bx in men with PSA between 3-10 ng/mL.