P004 Prostate cancer risk stratification based on a novel mathematical model developed by combining multiple clinical, biochemical and prostate imaging diagnostic parameters

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Introduction & Objectives: This proof of concept study was conducted with the aim to investigate the clinical applicability of a novel mathematical formula predicting the probability of diagnosing prostate cancer (PCa) in men suspected of harboring the disease, which was developed by combining a total of eight clinical, biochemical and imaging (prostate ultrasound and multiparametric MRI [mpMRI]) diagnostic variables.

Materials & Methods: We developed a logistic regression model analysis mathematical formula that incorporates clinical variables such as DRE and $pPCa_{PCRD}$ (measure of the probability of PCa diagnosis calculated based on PCRD-index, the main derivative of a previously reported mathematical formula [Clinical Genitourinary Cancer 2016,15(1):129-38] including age, prostate volume (PV) [ultrasonically determined], total PSA, free PSA, PSA-ratio, PSAD) as well as prostate mpMRI derived PIRADS score, to predict the probability (composite probability index termed $pPCa_{COMP}$]) of finding cancer on prostate biopsy. Subsequently, we applied this formula to a cohort of 28 men (65,8+/-7,2yo) with abnormal DRE and/or PSA measurements, who all were subjected to prostate mpMRI followed by extended TRUS guided biopsy (random plus cores from MRI designated ROIs). The predictive ability of $pPCa_{COMP}$ was then assessed compared to DRE, $pPCa_{PCRD}$ and PIRADS-score using univariable, linear regression and ROC curve analyses (SPSS-22©/MedCalc©/SciStat-p<0,05).

Results: Prostate cancer was diagnosed in 19 (68%) patients. On univariate analysis, age (p=0,5649), PV (p=0,0813), tPSA (p=0,894), fPSA (p=0,4346), PSAratio (p=0,2865) and PSAD (p=0,2972) did not differ significantly between the two groups (PCa[+]/PCa[-]) while, DRE was abnormal in 41,2% of positive biopsy patients (p=0,8723). Linear correlations showed that $pPCa_{COMP}$ was strongly (p<0,0001) positively related to cancer biopsy result followed by PIRADS-score (p=0,012) while, DRE (p=0,868) and $pPCa_{PCRD}$ (p=0,499)were insignificantly positively associated. On ROC-curve analysis, AUCs values were calculated as: $pPCa_{COMP}$=(0,875, p=0,03), PIRADS-score=(0,783, p=0,025), $pPCa_{PCRD}$=(0,695, p=0,123), DRE=(0,518, p=0,884), suggesting that $pPCa_{COMP}$ was comparatively the strongest predictor of cancer diagnosis, significantly differing from PIRADS-score (p=0,0016), $pPCa_{PCRD}$ (p<0,001) and DRE (p<0,0001).

Conclusions: The introduced novel prostate cancer diagnosis probability index, derived by combining eight disease associated variables, was found to accurately predict the outcome of prostate biopsy, significantly outperforming established clinical and imaging predictors of malignancy. These encouraging results justify our decision to proceed with larger scale study in order to validate findings and further expand the clinical utility of this innovative PCa risk stratification tool.