Assessment of a urinary TRUS/biomarker-based risk score as an inclusion criteria for multiparametric MRI to detect clinically significant prostate cancer.

Geert Trooskens,1 Daphne Hessels,2 Jack Schalken,3 Wim Van Creninge,4

1MDxHealth BV, Nijmegen, The Netherlands; 2Radboud University Medical Center, Nijmegen, The Netherlands; 3Ghent University, Ghent, Belgium;

BACKGROUND

Non-invasive techniques like urinary biomarkers and Magnetic Resonance Imaging (MRI) show great promise for the detection of clinically significant prostate cancer, leading to a reduction of over-diagnosis and over-treatment. Apart from yet to be established diagnostic accuracy is the systematic use of MRI challenging due to the high cost of setting up, staffing and maintaining a MRI unit. Upfront risk stratification could significantly lower the cost of multiparametric MRI (mpMRI) by excluding very low risk subjects for high grade prostate cancer.

AIM OF THE STUDY

The aim of this study was to assess how an established urinary biomarker-based risk score (SelectMDx) combined with transrectal ultrasonography (TRUS) could be used to exclude low-risk subjects from undergoing the mpMRI procedure.

METHODS

• The analysis was performed on a previously published (1) patient cohorts (A, n=529 and B, n=386) using a commercially available biomarker-based risk score model (SelectMDx).
• Of these two cohorts (A and B) 144 subjects underwent mpMRI (2) and TRUS on their first biopsy. The biomarker-based risk score model SelectMDx combined with TRUS was calculated, together with their PI-RADS scores (version 2).
• The inclusion cut-off for the model was set to 10% chance for high grade prostate cancer (Gleason Score 3+4 or higher).
• Positive MRI is defined as PIRADS score 4 or 5.
• 23 Samples showed prostate cancer with a Prostate Gleason Grade (PGG) of 2 (GS=3+4) upon biopsy. 27 had a PGG Grade higher then 2 (GS=4+3) (Figure 1)

RESULTS

Figure (1) Workflow and results of the biomarker-based risk score model SelectMDx with TRUS data as an inclusion criteria for mpMRI.

![Workflow and results of the biomarker-based risk score model SelectMDx with TRUS data as an inclusion criteria for mpMRI.](image)

Summary

• The performance of the model to detect PGG 2 and PGG3 or higher was determined on cohort A+B (Figure 2).
• SelectMDx showed an AUC of 0.89 corresponding to a sensitivity of 90% and a specificity of 59%.
• Analysis of the subset of 144 samples with mpMRI data (Figure 1) determined that SelectMDx+TRUS missed only 1 PCAa sample with a PGG grade of 2 (9.7%) and none with a PGG grade of 3 or higher.
• MRI missed one sample with a PGG grade of 3.
• The test can avoid 31% (48/94) of the unnecessary MRIs in the healthy and non-significant PCA (PGG=1) patients and 35% of all MRIs in this cohort.

Figure (2) Receiver Operator Curve (ROC) of SelectMDx and PCA3 on the total amount of samples in both cohorts (A+B). Performance is based on detection of PGG Grade 2 or higher.

![Receiver Operator Curve (ROC) of SelectMDx and PCA3 on the total amount of samples in both cohorts (A+B).](image)

CONCLUSIONS

This study clearly shows that the biomarker based SelectMDx risk score combined with TRUS information are resulting in significant reduction of over-diagnosis and over-treatment and may forgo unnecessary MRI procedures. It is thus recommended to perform SelectMDx as an exclusion criteria for MRI.

1. Van Nest L et al., Eur Urol 2016; 70:740-748