

Prostate Cancer 2

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340 Diagnostic utility of OPKO 4kScore® test combined with mpMRI or Select MDx urine test for patients with suspicion of prostate cancer

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Abstract

Purpose:

Opko Health's 4kScore®, MDxHealth's® Select MDx, and multiparametric magnetic resonance imaging (mpMRI) can help in prostate cancer diagnosis. We delineated the diagnostic precision of these tests and additional contributions of their combination.

Methods:

Retrospective review of 615 patients presented with elevated PSA or suspicion of prostate cancer since beginning of 2017 was performed. Abnormal tests were defined as mpMRI utilizing PI-RADS™ v2 criteria with a score of 4 or above, Select MDx™ risk for prostate cancer of 20% or above, or a 4kScore of $\geq 7.5\%$. Clinically significant positive prostate cancer diagnosis was defined as a primary Gleason sum of $\geq 3+4=7$. Diagnostic performance of 4K score was tested alone and in combination with other tests

Results Summary:

A total of 615 subjects were identified, 215 of which underwent an MRI/TRUS fusion prostate biopsy, mean age at time of baseline PSA was 64.4 years, mean PSA value at baseline was 7.49 ng/mL, 159 had a PI-RADS score of 4 and above, 211 had the 4kScore® Test performed, and 94 had the SelectMDx™ test performed. 4K score had high sensitivity 93% and NPV 91% but low specificity 28% and PPV 32%. Adding MRI or Select MDx increased NPV to 95%. Combination of Select MDx increased diagnostic accuracy with specificity of 67% and PPV 55% and saved 47% of patients from having prostate biopsies.

Conclusions:

OPKO 4K score is a test with high sensitivity and NPV in patients with suspicion of prostate cancer. Combination with MRI or Select MDx increases diagnostic accuracy. Combination of 4K score and Select MDx can be a good diagnostic next step before MRI or prostate biopsies in patients with elevated PSA or abnormal DRE.

Tables:

Table 1: Predictive Model Performance by Individual and Combined Formats									
OPKO Alone*	Biopsied Patients (N=211)				All Patients Despite Biopsy Status (N=587)				
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV	
0.375	0.65 (0.55, 0.68)	0.28 (0.11, 0.56)	0.52 (0.35, 0.40)	0.61 (0.50, 0.68)	0.65 (0.55, 0.68)	0.28 (0.15, 0.54)	0.16 (0.15, 0.14)	0.68 (0.50, 0.60)	
0.37	0.71 (0.60, 0.84)	0.71 (0.64, 0.73)	0.40 (0.35, 0.60)	0.88 (0.81, 0.95)	0.71 (0.60, 0.84)	0.68 (0.61, 0.71)	0.26 (0.11, 0.17)	0.65 (0.50, 0.56)	
0.33	0.68 (0.55, 0.80)	0.78 (0.65, 0.87)	0.61 (0.40, 0.65)	0.87 (0.80, 0.90)	0.68 (0.55, 0.80)	0.79 (0.67, 0.77)	0.51 (0.35, 0.40)	0.65 (0.50, 0.56)	
SelectMDx (20% Risk Any PCA)**	Biopsied Patients (N=105)				All Patients Despite Biopsy Status (N=74)				
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV	
0.3/3	0.52 (0.36, 1.00)	0.52 (0.36, 0.71)	0.46 (0.25, 0.57)	0.52 (0.36, 1.00)	0.52 (0.36, 1.00)	0.34 (0.22, 0.41)	0.41 (0.11, 0.25)	0.50 (0.27, 1.00)	
0.47	0.62 (0.36, 0.90)	0.89 (0.71, 0.90)	0.77 (0.46, 0.90)	0.52 (0.36, 0.99)	0.62 (0.36, 0.90)	0.60 (0.30, 0.79)	0.22 (0.11, 0.20)	0.50 (0.26, 0.99)	
0.21	0.62 (0.36, 0.90)	0.89 (0.71, 0.90)	0.77 (0.46, 0.90)	0.52 (0.36, 0.99)	0.62 (0.36, 0.90)	0.74 (0.36, 0.94)	0.20 (0.20, 0.09)	0.50 (0.26, 0.99)	
SelectMDx (20% Risk Any PCA)**	Biopsied Patients (N=105)				All Patients Despite Biopsy Status (N=74)				
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV	
0.375	0.69 (0.60, 1.00)	0.67 (0.48, 0.85)	0.55 (0.30, 0.77)	0.55 (0.24, 1.00)	0.69 (0.60, 1.00)	0.66 (0.57, 0.85)	0.26 (0.14, 0.40)	0.67 (0.54, 1.00)	
0.37	0.85 (0.70, 0.98)	0.68 (0.61, 1.00)	0.61 (0.30, 1.00)	0.65 (0.36, 0.99)	0.85 (0.70, 0.98)	0.75 (0.60, 0.85)	0.37 (0.10, 0.58)	0.66 (0.60, 0.99)	
0.34	0.85 (0.70, 0.98)	0.68 (0.61, 1.00)	0.61 (0.30, 1.00)	0.65 (0.36, 0.99)	0.85 (0.70, 0.98)	0.77 (0.60, 0.87)	0.40 (0.10, 0.85)	0.66 (0.60, 1.00)	
PIRADS (4)***	Biopsied Patients (N=102)				All Patients Despite Biopsy Status (N=277)				
	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV	
0.375	0.69 (0.60, 0.98)	0.68 (0.45, 0.87)	0.48 (0.34, 0.75)	0.68 (0.67, 0.69)	0.69 (0.60, 0.98)	0.69 (0.48, 0.79)	0.59 (0.34, 0.40)	0.67 (0.50, 0.99)	
0.37	0.79 (0.78, 0.85)	0.85 (0.75, 0.89)	0.61 (0.48, 0.75)	0.88 (0.80, 0.95)	0.79 (0.78, 0.85)	0.76 (0.70, 0.81)	0.41 (0.34, 0.59)	0.69 (0.67, 0.99)	
0.38	0.68 (0.50, 0.78)	0.88 (0.75, 0.95)	0.64 (0.30, 0.78)	0.87 (0.80, 0.95)	0.68 (0.50, 0.78)	0.86 (0.74, 0.80)	0.44 (0.35, 0.59)	0.61 (0.60, 0.94)	

**10% of patients were processed by prostate core biopsy and diagnosis based on review with 95% core biopsy in the same patient. This report was processed in a single fashion.
 *** SelectMDx risk for diagnosis of prostate cancer at level of 20% combined with 40% of core biopsy in the same patient.
 **** SelectMDx risk for diagnosis of prostate cancer at level of 30% combined with 40% of core biopsy in the same patient.
 ***** SelectMDx risk for 4 core biopsy in the same patient.