

320 Title: Diagnostic performance of ExosomeDx™ 's ExoDx™ Prostate Test and Opko Health's 4kScore ®Test by Intelliscore threshold

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Abstract

Purpose:

ExosomeDx™ 's ExoDx™ Prostate Test , Opko Health's 4kScore ®Test, and multiparametric magnetic resonance imaging (mpMRI) predict prostate cancer diagnosis. We aimed to estimate the diagnostic precision of these tests and additional contributions of a combined predictive model stratified by three different Intelliscore thresholds.

Methods:

Chart review was conducted between 1/2017 & 3/2020 for patients with the following clinical measures : mpMRI PI-RADS score , MRI/TRUS fusion targeted prostate biopsy, 4kScore ® Test and ExoDx™ Prostate Test. The PI-RADS™ v2 criteria was used to evaluate mpMRI with a score of 4 or above and a 4kScore of 7.5% and greater was also used to indicate necessity for biopsy. Prostate cancer diagnosis was defined as a primary Gleason sum of 3+3=6 and above. Binary classification tests including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were performed to estimate precision of the aforementioned tests and estimated at three cut-off points based on ExoDx's prostate intelliscore.

Results:

A total of 295 subjects underwent the MRI/TRUS fusion biopsy, 42 had abnormalities on initial DRE, mean age at time of baseline PSA was 64.4 years, mean PSA value at baseline was 7.49 ng/mL, 113 of which underwent the ExoDx™ Prostate Test and 211 of which had the 4kScore ® Test performed. Mean 4kScore ® was 0.303 and mean ExoDx™ Prostate Intelliscore was 28.45. ExoDx showed the highest sensitivity (86%) and NPV(91%) at

Prostate Intelliscore threshold of 15. Combination of PI-RADS score of 4 and above with ExoDx had the highest sensitivity (86%), specificity (71%), and NPV (93%) at threshold of 15. 4kScore combined with ExoDx had the highest sensitivity (90%) and NPV (97%) at a threshold of 15, however, a threshold of 23 demonstrated better performance for sensitivity (80%), sensitivity (79%), and NPV (94%).

Conclusion:

Our data suggests that combined OPKO4kScore ® Test and ExoDx™ Prostate Test outperformed ExoDx test alone and in combination with mpMRI. This combination of biomarkers can potentially be an initial step to evaluate and select patients with elevated PSA for prostate biopsies.

Table 1. Precision comparisons of ExoDx only, ExoDx and mpMRI, and OPKO 4kScore and ExoDx combined.								
Biopsied Patients: (N=113)					All Patents Despite Biopsy Status: (N=290)			
ExoDx Alone*	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV
15	0.86 (0.65, 0.97)	0.33 (0.23, 0.44)	0.24 (0.15, 0.35)	0.91 (0.76, 0.98)	0.86 (0.65, 0.97)	0.35 (0.29, 0.41)	0.10 (0.06, 0.15)	0.97 (0.91, 0.99)
Biopsied Patients: (N= 52)					All Patents Despite Biopsy Status: (N=106)			
MRI (PIRADS $\geq 4 = +$)**	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV
15	0.86 (0.57, 0.98)	0.71 (0.54, 0.85)	0.52 (0.31, 0.73)	0.93 (0.77, 0.99)	0.86 (0.57, 0.98)	0.67 (0.57, 0.77)	0.29 (0.16, 0.45)	0.97 (0.89, 1.00)
Biopsied Patients: (N= 52)					All Patents Despite Biopsy Status: (N=130)			
4kScore ($\geq 0.075 = +$)***	Sensitivity	Specificity	PPV	NPV	Sensitivity	Specificity	PPV	NPV
15	0.90 (0.55, 1.00)	0.67 (0.50, 0.80)	0.39 (0.20, 0.61)	0.97 (0.82, 1.00)	0.90 (0.55, 1.00)	0.54 (0.45, 0.63)	0.14 (0.07, 0.25)	0.98 (0.92, 1.00)

* ExoDx alone is presented by predictive modeling and displays point estimates with 95% confidence intervals adjacent. This value measures each predictive outcome by different ExoDx intelliscore thresholds.

** MRI (PIRADS $\geq 4 = +$) subjects must have a collected PI-RADS imaging score of 4 or greater to be included. Predictive outcomes shown are for the combined estimation of both mpMRI and subjects with the ExoDx test separately by different ExoDx intelliscore thresholds.

*** 4kScore ($\geq 0.075 = +$) is presented by predictive modeling and displays point estimates with 95% confidence intervals adjacent. Predictive outcomes shown are for the combined estimation of both OPKO 4kScore and subjects with the ExoDx test separately by different ExoDx intelliscore thresholds.