Clinical utility of SelectMDx and Prostate Health Index for diagnosis of high-grade prostate cancer

Gretchen P. Hoyer, E. David Crawford, MD, Paul Arangua, Whitney N. Stanton, Francisco G. La Rosa, MD, Wendy Poage[1], M. Scott Lucia, MD, Adrian van Bokhoven, PhD, and Priya N. Werahera, PhD

University of Colorado Anschutz Medical Campus, Aurora, CO;

[1]Prostate Condition Education Council, Aurora, CO

- Compared the performance of Prostate Health Index (phi) and SelectMDx in the diagnosis of any prostate cancer and the diagnosis of high-grade prostate cancer

- SelectMDx and phi compared to transperineal 3D mapping biopsies (TMB), which has a diagnostic accuracy of 98% (Figure 1)

- phi < 27 indicates patient free of prostate cancer, SelectMDx score = 0% indicates patient free of high-grade prostate cancer

Figure 1: TMB prostate cancer map from histopathology data

- 70 patients selected who had TMB
  - 17/70 had no prostate cancer
  - 53/70 with prostate cancer
  - 22/53 with high-grade prostate cancer

- Data analyzed with multivariate logistic regression (MLS) and receiver operating characteristic curves

- DeLong test was used to determine statistical significance of ROC curves
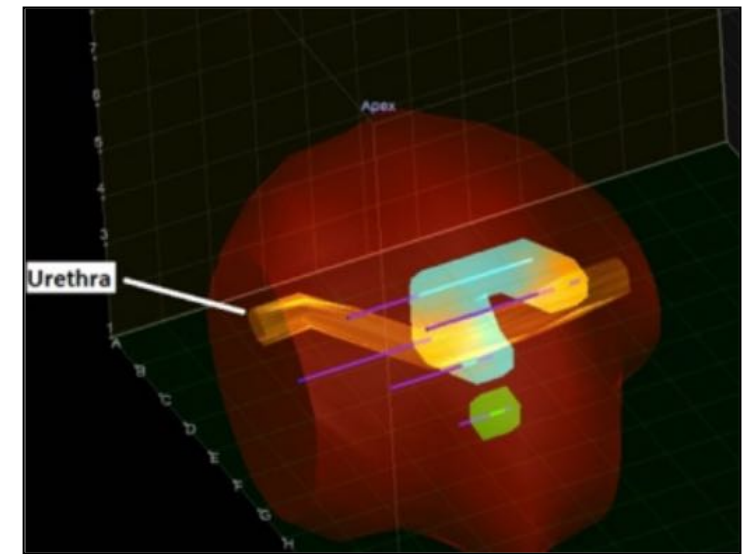
	Age	PSA	Free PSA	% Free PSA	P2PSA	PHI score
Median	65	2.83	0.44	0.17	11.9	41.82
Mean	63.21	3.58	0.55	0.18	15.85	47.10
Standard Dev.	8.12	3.33	0.51	0.10	16.86	46.38

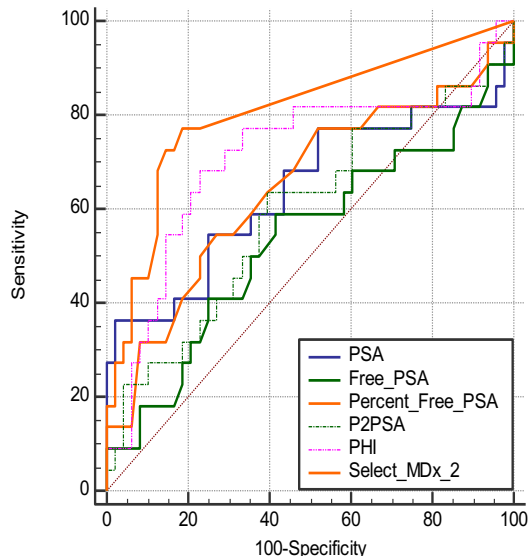**Figure 2:** Demographic data for the participants

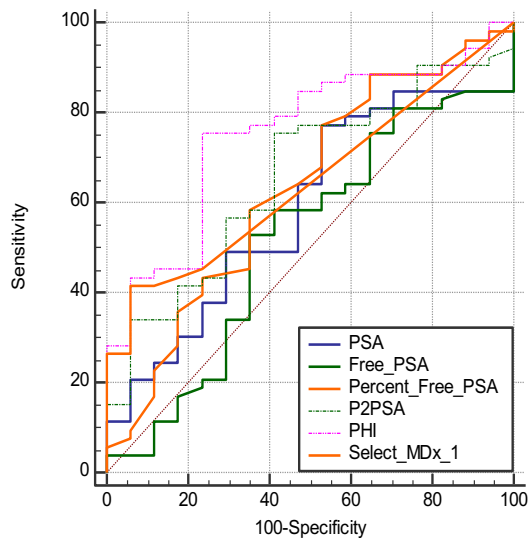Figure 3: ROC comparison for diagnosis of high- grade prostate cancer

Figure 4: ROC comparison for diagnosis of any prostate cancer

Any PCa (3+3 or higher)	
Comparison	*P value*
PHI vs. PSA	0.0190
P2PSA vs. Free PSA	0.0045
PHI vs. Free PSA	0.0152
Select MDx vs. PHI	0.1712

High-grade PCa (3+4 or higher)	
Comparison	*P value*
Free PSA vs. PSA	0.0276
PHI vs. Free PSA	0.0461
Select MDx vs. % Free PSA	0.0494
PHI vs. P2PSA	0.0497
Select MDx vs. P2PSA	0.0109
Select MDx vs. PHI	0.2248

Figure 5: p values for ROC comparisons of any prostate cancer and high-grade prostate cancer

Test	Any PCa (Gleason scores ≥ 6)				High-grade PCa (Gleason scores ≥ 7)			
	Sensitivity	*Specificity*	*PPV*	*NPV*	*Sensitivity*	*Specificity*	*PPV*	*NPV*
phi	79%	53%	84%	45%	50%	85%	61%	79%
SelectMDx	45%	77%	86%	31%	82%	75%	60%	90%

Figure 6: sensitivity, specificity, NPV, and PPV for any PCa and high-grade PCa

	Any PCa (3+3 and higher)	HG PCa (3+4 and higher)
Best model fit	phi	SelectMDx
Significance Level	0.0006	<0.0001
Coefficient	0.054	8.45
P value	0.005	0.0002

Figure 7: sensitivity, specificity, NPV, and PPV for any PCa and high-grade PCa

- ROC comparison did not show a significant difference between phi and SelectMDx
- MLS showed that SelectMDx is significantly better at diagnosing high-grade prostate cancer, while phi is significantly better at diagnosing any prostate cancer
- **Conclusion: Select MDx is more useful than phi for screening patients at risk of high-grade PCa prior to biopsy**