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Clinical utility of biomarkers 4K score, SelectMDx and ExoDx with MRI for the detection of high-grade prostate cancer.

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Abstract Disclosures

Background:

Although adoption of new biomarkers and MRI has become widespread, their utility when deciding to biopsy is unclear. We aim to evaluate and compare 4K, SelectMDx, ExoDx and their added value when combined with prostate MRI in the detection of high-grade prostate cancer (HG PC) and avoidance of unnecessary biopsies.

Methods:

Patients referred for consideration of prostate biopsy at UCSF between 2016-2019 were enrolled and had either 4K, SelectMDx or ExoDx testing with/without MRI. Logistic regression and AUC were used to determine the performance of each biomarker in detecting HG PC ($\geq$Gleason grade (GG) 3+4). In the subgroup of patients that underwent biopsy, with PSA 2.5-10 and negative DRE, we determined the

number of avoided unnecessary biopsies (with GG 3+3 cancer or no cancer) and missed HG PC for each biomarker with/without MRI.

Results:

A total of 896 patients were enrolled, 457 were biopsied. Mean age was 65.5 years, median PSA was 6.32. Logistic regression showed that having an abnormal biomarker score or PI-RADS 4/5 on MRI (P4/5) was strongly associated with finding HG PC: 4K OR 12.9 (CI 4.58-36.1), ExoDx OR 14.7 (CI 3.31-65.3), SelectMDx OR 3.62 (CI 1.44-9.11), P4/5 OR 6.20 (CI 3.93-9.79), TRUS ≥T2a OR 4.33 (CI 2.78-6.75), PSAD >0.15 OR 4.01 (CI 2.59-6.20), p<0.01). Combining biomarker and P4/5 lesion on MRI increased AUC for detecting HG PC. In the biopsy subgroup, a normal 4K or ExoDx test missed only 4-5% HG PC, while an abnormal test resulted in avoiding 14-20% unnecessary biopsies. Combining MRI with ExoDx or 4K missed 0-1.43% HG PC but avoided only 7-9% unnecessary biopsies (Table).

Conclusions:

4K and ExoDx outperformed MRI and SelectMDx but combining the biomarkers with MRI resulted in the best predictive ability for detecting HG PC. Negative MRI avoided more biopsies than a normal 4K or ExoDxbut missed more aggressive cancers. Our data suggest that MRI alone is not sensitive enough to detect all HG PC and that 4K or ExoDx testing alone could be sufficient when deciding to proceed with biopsy.

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	% Avoided biopsies	% Missed HG PC
4K	14.2	5.7
ExoDx	19.7	4.35
SelectMDx	49.0	53.8
TRUS ≥T2a	46.5	26.3
PSAD >0.15	61.0	45.3
P4/5	54.2	35.7
4K and P4/5	6.85	1.43
ExoDx and P4/5	9.09	0
SelectMDx and P4/5	20.4	23.1