Is Prostate Cancer Screening and Risk Stratification Moving Beyond the PSA Test?
Four new studies highlight important research in the field of prostate cancer markers

SAN FRANCISCO, May 18, 2018 /PRNewswire-USNewswire/ -- New diagnostic tests for prostate cancer, as well as new information about the impact of the U.S. Preventive Services Task Force recommendations on prostate cancer screening will be presented this year during the 113th Annual Meeting of the American Urological Association (AUA). Four studies highlighting these topics will be shared during a special press conference on May 18 at 8:30 a.m. (PT). Stacy Loeb, MD, AUA spokesperson and assistant professor of urology and population health at New York University will moderate this session for media.

Study Details
Publication #: PD52-11

PSA Screening of African-American Veterans Before, During and After Implementation of the 2012 U.S. Preventive Services Task Force Recommendations:

Prostate cancer screening rates at Department of Veterans Affairs' clinics declined for both African-American and non-African-American men following the release of the 2012 prostate cancer screening recommendations from the U.S. Preventive Services Task Force (USPSTF), according to this multi-institutional study. Researchers examined prostate-specific antigen (PSA) screening rates for male veterans aged 40 to 80 without a diagnosis of prostate cancer who visited a VA primary care or urology clinic between 2009 and 2016, and assessed the differential effect of the USPSTF policy change on screening rates. Results were assessed for the pre-guidelines period (2009-2010), the transition period (2011-2014) and the post-guideline period (2015-2016), and showed:

- Prior to the release of the USPSTF recommendations, African-American veterans underwent PSA screening more often at the VA than non-African-American veterans. However, across the years of the study, the percentage of PSA-eligible men who received a test decreased yearly (from 63 percent in 2009 to 51 percent in 2016).
- PSA screening rates in the pre-guidelines period show a 6 percent decrease for African-American veterans and a 6.3 percent decrease for non-African-American veterans.
- During the transition period, the screening rate for African-American veterans decreased by 12.7 percent, and the rate for non- African-American veterans decreased by 12.8 percent.
- During the post-guideline period, screening rates continued to decrease, with African-American veterans experiencing a 3.5 percent decrease and non- African-American veterans a decrease of 3.6 percent.

Study Details:
Publication #: PD06-09

Prostate Cancer Genomics: Comparing Decipher, Prolaris and OncotypeDx Results:
The use of genomic tests to predict outcomes and guide treatment for prostate cancer is growing, but discrepancies exist between these tests and their recommendations for treatment versus active surveillance (AS). Researchers from Hartford, CT, reviewed three unique tests (Decipher, Prolaris and OncotypeDX) to evaluate genomic test results and the potential implications of their results on eligibility for AS.

By performing a retrospective chart review, researchers identified 22 patients who underwent at least two of these genomic tests at Hartford Hospital between 2014 and 2017. Results were compared to genomic standards for AS appropriateness based on guidelines from the National Comprehensive Cancer Network (NCCN). Percentage agreement rates were calculated, and kappa statistic (k) was used to obtain proportion of agreement over and above chance.

Results showed:

- AS would be recommended for 21 out of 22 patients based on NCCN guidelines.
- For the 12 patients who received both the Decipher and Prolaris tests, percentage agreement was 67 percent and k was 0.31 (p=.276).
- For the eight patients who received Prolaris and OncotypeDx, percentage agreement was 75 percent and k was 0.39 (p=.168), with Prolaris tending to favor AS over surgery.
- Two patients received both Decipher and OncotypeDX. These tests together yielded a 50 percent agreement and an incalculable k.
- When compared to NCCN guidance, Prolaris had a 75 percent agreement and .21 k (p=.117, N=20); Decipher had a 60 percent agreement and k of .15 (p=.268, N=15); and OncotypeDX had an agreement of 50 percent with an incalculable k.

Study Details:
**Prospective Validation of the IsoPSA™ Assay for Detection of High Grade Prostate Cancer:** Early studies have demonstrated that IsoPSA™, a structure-focused protein biomarker, may be an effective means of discriminating between high-grade prostate cancer (Gleason≥7) and low-grade (Gleason=6)/benign disease. This multi-center study validated the clinical performance of IsoPSA in follow-up to the preliminary study. Plasma samples were obtained from clinical sites within 30 days prior to biopsy from patients with PSA between 2 ng/mL and 62.8 ng/mL, and IsoPSA results were evaluated against results from 12-core TRUS biopsies. In the preliminary study, 33.7 percent of the cohort had high-grade prostate cancer, and 32.6 percent of the validation cohort had high-grade prostate cancer.

Results showed:

- ROC analysis of the preliminary and validation studies resulted in AUC of 0.81 vs. 0.82 respectively.
- Using the cutoff value established in the preliminary study (KR-HG risk probability <17 percent), the validation study demonstrated a negative predictive value of 93.3 percent, compared to 94 percent as seen in the preliminary study.
- More than 40 percent of biopsies could have been avoided in both the preliminary study (45.1 percent) and validation study (47 percent).

**Study Details:**
Publication #: MP40-10

**Extended Validation Results from a Prospective Adaptive Utility Trial Confirm Performance of a Novel Urine Exosome Gene Expression Assay to Predict High-Grade Prostate Cancer at Initial Biopsy:** A new class 3-gene expression urine assay for prostate cancer – ExoDx Prostate IntelliScore, or EPI – may help identify patients with higher grade disease and could help reduce unnecessary biopsies. This extended validation study assessed outcome and cut-point performance for EPI test results compared with biopsy outcomes.

The validation cohort was comprised of 504 men with a mean age of 64 years and a mean PSA of 5.6 ng/mL. Fifty-three percent of the men had a positive biopsy, with 22 percent having a Gleason score of 6, 17 percent having a Gleason score of 3+4 and 14 percent having a Gleason score of 4+3.

Results showed:

- Using ROC analysis, the EPI AUC was 0.70, compared to AUC of 0.62 for standard of care (PSA, age, race, family history) for discriminating high-grade disease from low-risk/benign disease.
- Using the (previously validated) cut point of 15.6 (or alternative 20) would avoid 26 percent (or 40 percent) of unnecessary prostate biopsies and 20 percent (or 31 percent) of total biopsies, with a negative predictive value of 89 percent for both cut points.

"These studies highlight important research in the field of prostate cancer screening, including the potential negative impact of the 2012 USPSTF recommendations on screening in high-risk populations," said Dr. Loeb. "At the same time, the field of prostate cancer screening and risk stratification is moving beyond the PSA test, and these studies show there are a few exciting new markers on the horizon."

**About the American Urological Association:** The 113th Annual Meeting of the American Urological Association takes place May 18-21 at the Moscone Center in San Francisco, CA.

Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association is a leading advocate for the specialty of urology, and has more than 21,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

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