Analysis of a Circulating Microvesicle-Based Assay in At-Risk Patients for the Detection of Prostate Cancer

Adam S. Kibel1, Gerald L. Andriole1, Daniel W. Lin2, Robert L. Vessella3, Steven P. Stratton3, Raymond Nagle3, Mitchell H. Sokoloff3, Amit Algotar3, Frederick Ahman3, James Mobley4, David B. Spetzler5, Christine D. Kuslich5

1 - Division of Urology, Department of Surgery, St. Louis; MO; 2 - Department of Urology, University of Washington, Seattle, WA; 3 - Arizona Cancer Center and Section of Urology, University of Arizona College of Medicine, Tucson, AZ; 4 - UAB MSP Facility, The University of Alabama at Birmingham, AL; 5 - Research and Development Division, Caris Life Sciences, Phoenix, AZ

ABSTRACT

Purpose: While PSA-based testing has improved the ability to detect prostate cancer (PCa), it is limited by low sensitivity and specificity. Circulating microvesicles (cMV) are membrane-bound structures in the blood that carry material from their cell of origin. Previous studies have found microvesicles that correlate with the presence of disease. The aim of this study was to evaluate a novel cMV-based assay for the detection of PCa.

Methods: The assay was developed by selecting antibodies to protein biomarkers based on their ability to differentiate between men with and without PCa. The antibodies to specific biomarkers were evaluated using retrospective frozen plasma samples from men with biopsy-confined, non-metastatic PCa (N=551) and controls (N=97). Prostate-specific cMV were captured and analyzed. Samples were blindly classified as positive, negative, or borderline according to Median Fluorescence Intensity (MFI) values acquired by a flow cytometry-based method.

Results: The assay was successfully run on 58 of 69 (85%) samples of cases and controls. Pre-analytic sample collection conditions (e.g., centrifugation, temperature) resulted in 100% samples having analyzable high MFI, and there was no result for the remaining 21. The overall sensitivity, specificity, and Balanced Operating Characteristic (BOC) curve were calculated.

Conclusion: The cMV-based prostate cancer test is a promising new assay for the detection of PCa with performance characteristics superior to serum PSA. While further validation in a larger prospective cohort is needed, this assay could significantly improve PCa detection and aid in informed decisions regarding invasive testing and therapy.

To determine if a circulating microvesicle-based immunoassay can be used to identify which patients have prostate carcinoma.

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