Decipher correlation patterns on biopsy: Initial experience from 738 prospective patients

Stacy Loeb[1], Ashley E. Ross[2], María Santiago-Jiménez[3], **Zaid Haddad[3]**, Qiqi Wang[3], Lucia L.C. Lam[3], Kasra Yousefi[3], Elai Davicioni[3], Felix Y. Feng[4], Eric A. Klein[5], Robert B. Den[6], Daniel E. Spratt[7]

1. Department of Urology and Population Health, New York University and Manhattan Veterans Affairs Medical Center, NY, USA
2. James Buchanan Brady Urological Institute, Johns Hopkins Hospital, Baltimore, MD, USA
3. GenomeDx Biosciences Inc. Vancouver, BC, Canada
4. Department of Radiation Oncology, Helen Diller Family Comprehensive Cancer Center, University of California at San Francisco, CA, USA
5. Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA
6. Department of Radiation Oncology, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, USA
7. Department of Radiation Oncology, Michigan Center for Translational Pathology, Comprehensive Cancer Center, University of Michigan, Ann Arbor, MI, USA

Abstract

Background: The 22-gene test (Decipher) developed for post-prostatectomy patients, has recently been evaluated on biopsy specimens to predict metastasis. Here, we examined the relationship between the Decipher scores and clinicopathologic characteristics.

Methods: De-identified Decipher test results (including Decipher risk scores and clinical data) from 738 consecutive biopsy specimens tested between February and May 2016 were analyzed. Decipher scores were calculated based on a previously locked model. Spearman's rank correlation and Fisher's exact were used to test the association between biopsy Decipher and clinical variables and risk models.

Results: Overall, 40.5%, 32%, 14%, 8.5% and 5% of patients were categorized as biopsy grade group (GG) 1, 2, 3, 4 and 5, respectively. Sixty-eight percent of patients had <50% positive cores; 78% had cT1c. Among patients with known NCCN risk group, 26%, 52% and 22% were categorized as NCCN low, intermediate and high risk, respectively. Biopsy Decipher classified 37%, 25%, and 38% of patients as low, intermediate and high-risk, respectively. Decipher had a moderate correlation of 0.41 (95% confidence interval [CI] 0.35-0.47) and 0.39 (95% CI 0.31-0.46) with GG and NCCN risk, respectively. Among patients with GG1 and GG5, 21% and 82% of patients were classified as high-risk by Decipher, respectively ($p<0.001$). Among NCCN intermediate risk patients, Decipher showed a significant risk differential between favorable and unfavorable sub-groups with 43% and 26% as Decipher low-risk, respectively ($p=0.001$).

Conclusions: In the first prospective analysis of biopsy Decipher in over 700 patients, Decipher showed moderate correlation with clinical variables but significantly reclassified tumor aggressiveness determined by clinical variables alone. Utilization of the biopsy Decipher test can have major implications in assessment of risk at diagnosis and may impact physician-patient decision making and ultimately patient management.

Conflict of Interests: MSJ, ZH, QW, LLCL, KY and ED are employees of GenomeDx Biosciences.

Funding Acknowledgements: GenomeDx Biosciences sponsored this study.