19-6304

PROSPECTIVE RANDOMIZED TRIAL OF GENE EXRESSION CLASSIFIER UTILTY IN MEN AT HIGH RISK OF RECURRENCE FOLLOWING RADICAL PROSTATECTOMY

*Todd Morgan *, Linda Okoth, Ann Arbor , MI, Felix Feng, San Francisco, CA, Anna Johnson, Ann Arbor , MI, Brian Lane, Grand Rapids, MI, Susan Linsell, Khurdish Ghani, James Montie, Ann Arbor , MI, Nick Fishbane, Tara Marti, Marguerite du Plessis, Vancouver, Canada, Rohit Mehra, Ann Arbor , MI, Elai Davicioni, Vancouver, Canada, Thomas Maatman, Grand Rapids, MI, Kirk Wojno, Frank Burks, Royal Oak, MI, Paul Rodriguez, Grand Rapids, MI, Nick Liu, Ypsilanti , MI, Richard Sarle, Troy, United Kingdom, David Miller, Ann Arbor , MI, Michael Cher, Detroit, MI, Michigan Urological Surgery Improvement Collaborative, Ann Arbor, MI*

INTRODUCTION AND OBJECTIVES: The Decipher assay is a tissue-based genomic classifier (GC) developed and validated in the post-radical prostatectomy (RP) setting as a predictor of metastasis. Retrospective evidence suggests that patients with a high GC score may benefit from adjuvant radiotherapy, while observation may be safe for those with a lower GC score. We sought to conduct the first prospective randomized trial assessing the impact of GC testing on adjuvant therapy use in this setting and report here patient characteristics and risk distribution of the cohort.

METHODS: The Genomics in Michigan ImpactiNg Observation or Radiation (G-MINOR) study enrolled 356 participants across 13 sites between January 2017-August 2018. Eligible patients had undergone RP within 9 months of enrollment, had pT3-4 and/or positive surgical margins, and a post-RP PSA <0.1ng/mL. Patients were assigned to either the GC or Usual-Care-Based (UC) group using cluster-crossover block randomization assignments. Patients in both arms received a CAPRA-S derived predicted risk of recurrence. If enrolled during the GC period, the subject and physician were also provided with the Decipher score. Decipher results were assessed centrally in UC patients but were not available to clinicians or patients. Clinical data, including CAPRA-S and Decipher scores, were compared between arms.

RESULTS: We report on 356 patients that met the inclusion criteria and whose RP tissue passed the required QC thresholds. Of these patients, 182 (51.1%) and 174 (48.9%) were randomized to the GC and UC groups, respectively. Between study arms, we found no statistically significant difference in the frequency of extraprostatic extensions, seminal vesicle invasion, or surgical margins; nor did we find a difference in distribution of Gleason grade, pre-operative PSA, or CAPRA-S score. Based on the Decipher scores, the risk of metastasis within 5-years of RP had a median (IQR) of 6.0% (2.4%-16.8%) in the GC group and 6.9% (2.6%-19.5%) in the UC group (Wilcoxon p=0.45).

CONCLUSIONS: In this biomarker-driven clinical trial of men following RP, baseline clinical variables, CAPRA-S risk, and Decipher scores were similar in the two study arms. With completion of enrollment, these data indicate the study will be appropriately powered to measure rates of post-operative radiation within 18 months from surgery and rates of metastasis within 5 years from surgery.

Source of Funding: GenomeDx Biosciences
Blue Cross Blue Shield of Michigan