Genomic Classifier Test Impacts Treatment Decision-Making among Patients with Biochemical Recurrence after Radical Prostatectomy: Results from the Multicenter Prospective PRO-IMPACT study

Scott Perrapato 1, John Gore 2, Marguerite du Plessis 3, Maria Santiago-Jimenez 5, Kasra Yousefi 5, Darby Thompson 4, David Chen 5, William Clark 6, Michael Franks 7, Lawrence Karsh 8, Adam Kibel 9, Brian Lane 10, Yair Lotan 11, William Lowrance 12, Paul Maroni 13, Edouard Trabulsi 14, Robert Waterhouse 15, Elai Davicioni 3, Daniel Lin 2.

1 University of Vermont Medical Center, Burlington, VT
2 University of Washington, Seattle, WA
3 GenomeDx Biosciences Inc., Vancouver, BC, Canada
4 EMMES Canada, Burnaby, BC, Canada
5 Fox Chase Cancer Center, Philadelphia, PA
6 Alaska Clinical Research Center, Anchorage, AK
7 Virginia Urology, Richmond, VA
8 The Urology Center of Colorado, Denver, CO
9 Brigham and Women's Hospital, Boston, MA
10 Spectrum Health Medical Group, Grand Rapids, MI
11 UT Southwestern Medical Center, Dallas, TX
12 Huntsman Cancer Hospital, Institute, University of Utah, Salt Lake City, UT
13 University of Colorado, Denver Medical Campus, Denver, CO
14 Thomas Jefferson University, Philadelphia, PA
15 Carolina Urology Partners, Gastonia, NC
Introduction and Objective
Patients and providers are tasked with tremendous uncertainty as they decide on the appropriate timing for intervention with salvage radiation therapy (SRT) for suspected local recurrence after radical prostatectomy (RP). We prospectively evaluated the impact of the Genomic Classifier (GC) test (GenomeDx Biosciences Inc., Vancouver), which predicts metastasis risk after RP, on urologists’ decision-making for SRT.

Subjects and Methods
75 salvage patients were enrolled into the study by 43 urologists from 19 community and academic practices. Patients with rising PSA after RP were included. For each patient, participating physicians were asked to provide a management recommendation prior to processing the GC test and again upon receiving the GC test results. Patients complete validated surveys on decisional quality and PCa-related anxiety and are followed for one year. In this interim analysis, we evaluated the pre- and post-GC visits.

Results
GC results were available for 69 patients. Median patient age at enrollment was 64 years; 45% had pathologic T3 stage classification and 49.3% had positive surgical margins at RP. The median 5-year predicted probability of metastasis by the GC test was 5.9% (interquartile range [IQR] 2.8%-12.1%). GC classified 35%, 32% and 33% as low-, intermediate-, and high-risk, respectively. Without GC, 58%, 33% and 8.7% of patients were recommended for observation, SRT, and other treatments, respectively. Overall, 39% (95% confidence interval 28-52%) of management recommendations changed post-GC, including 29% of GC low-risk patients and 65% of GC high-risk patients. Decisional Conflict Scale (DCS) scores decreased (indicating higher decision quality) after exposure to GC test results. Median DCS pre-GC was 28 (IQR 21-42) compared to 21 (IQR 2-28) post-GC (p<0.001).

Conclusions
Knowledge of GC test results was associated with treatment decision-making among patients with biochemical recurrence after RP. Patients found to be low risk for metastasis by GC had higher rates of observation recommendations and patients at high risk had higher rates of SRT recommendations. Decision quality was improved among patients considering SRT after RP exposed to their GC test results.

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