

**Genomic Classifier Test Impacts Adjuvant Treatment Decision-Making among Patients with High-Risk Pathology at Radical Prostatectomy: Results from the Multicenter Prospective PRO-IMPACT Study**

**Scott Perrapato<sup>1</sup>, John Gore<sup>2</sup>, Marguerite du Plessis<sup>3</sup>, Maria Santiago-Jimenez<sup>3</sup>, Kasra Yousefi<sup>3</sup>, Darby Thompson<sup>4</sup>, Mark Bandyk<sup>5</sup>, David Chen<sup>6</sup>, William Clark<sup>7</sup>, Michael Franks<sup>8</sup>, Lawrence Karsh<sup>9</sup>, Adam Kibel<sup>10</sup>, Hyung Kim<sup>11</sup>, Brian Lane<sup>12</sup>, Yair Lotan<sup>13</sup>, William Lowrance<sup>14</sup>, Paul Maroni<sup>15</sup>, Edouard Trabulsi<sup>16</sup>, Robert Waterhouse<sup>17</sup>, Elai Davicioni<sup>3</sup>, Daniel Lin<sup>2</sup>**

<sup>1</sup> University of Vermont Medical Center, Burlington, VT

<sup>2</sup> University of Washington, Seattle, WA

<sup>3</sup> GenomeDx Biosciences Inc., Vancouver, BC, Canada

<sup>4</sup> EMMES Canada, Burnaby, BC, Canada

<sup>5</sup> Lakeland Regional Cancer Center, Lakeland, FL

<sup>6</sup> Fox Chase Cancer Center, Philadelphia, PA

<sup>7</sup> Alaska Clinical Research Center, Anchorage, AK

<sup>8</sup> Virginia Urology, Richmond, VA

<sup>9</sup> The Urology Center of Colorado, Denver, CO

<sup>10</sup> Brigham and Women's Hospital, Boston, MA

<sup>11</sup> Cedars-Sinai Medical Center, Los Angeles, CA

<sup>12</sup> Spectrum Health Medical Group, Grand Rapids, MI

<sup>13</sup> UT Southwestern Medical Center, Dallas, TX

<sup>14</sup> Huntsman Cancer Hospital, Institute, University of Utah, Salt Lake City, UT

<sup>15</sup> University of Colorado, Denver Medical Campus, Denver, CO

<sup>16</sup> Thomas Jefferson University, Philadelphia, PA

<sup>17</sup> Carolina Urology Partners, Gastonia, NC

### **Introduction and Objective**

The decision to provide adjuvant therapy to men with high risk pathologic features following radical prostatectomy (RP) is confounded by tremendous uncertainty. 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 adjuvant treatment of high-risk prostate cancer (PCa) patients.

### **Subjects and Methods**

150 adjuvant patients were enrolled into the study by 43 urologists from 19 community and academic practices. Patients with pathologic T3 stage classification (pT3) or positive surgical margin (SM+) 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 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 141 patients. Median patient age at RP was 64 years; 66% and 51% of patients had pT3 and SM+ pathology, respectively. The median 5-year predicted probability of metastasis by the GC test was 5.0% (interquartile range [IQR] 2.2%-10.7%). GC classified 48%, 20% and 32% of men as low-, intermediate- and high-risk, respectively. Without GC, observation was recommended for 88% (n=124), and 12% (n=17) received a recommendation for adjuvant radiation therapy (ART). Overall, 18% (95% confidence interval [CI] 12-26%) of adjuvant treatment recommendations changed post-GC, including 9% of low-risk GC patients, and 31% of high-risk GC patients. Decisional Conflict Scale (DCS) scores decreased (indicating higher decision quality) after exposure to GC test results. Median DCS pre-GC was 25 (IQR 10-44) compared to 20 post-GC ( $p<0.001$ ). GC results were associated with the decision to pursue ART, adjusting for clinical and pathologic parameters in multivariable logistic regression (odds ratio 1.47; 95% CI 1.18-1.83;  $p<0.001$ ).

### **Conclusions**

Observation is the predominantly prescribed management strategy among PCa patients with high risk features at RP. Knowledge of GC test results was associated with treatment decision-making among these patients: 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 ART recommendations. Decision quality was improved for patients when exposed to GC test results.

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