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

John L. Gore¹, Marguerite du Plessis², Maria Santiago-Jimenez², Kasra Yousefi², Darby Thompson³ Mark Bandyk⁴, Fernando Bianco⁵, Gordon Brown⁶, David Chen⁷, William Clark ⁸, Michael Franks⁹, Lawrence Karsh¹⁰, Adam Kibel¹¹, Hyung Kim¹², Brian Lane¹³, Yair Lotan¹⁴, William Lowrance¹⁵, Murugesan Manoharan¹⁶, Paul Maroni¹⁷, Scott Perrapato ¹⁸ Paul Sieber¹⁹, Edouard Trabulsi²⁰, Robert Waterhouse²¹, Elai Davicioni², **Daniel Lin¹**,

¹University of Washington, Seattle, WA

²GenomeDx Biosciences Inc., Vancouver, BC, Canada

³ EMMES Canada, Burnaby, BC, Canada

⁴ Lakeland Regional Cancer Center, Lakeland, FL

⁵Urological Research Network; Columbia University Dept of Urology, Miami, FL

⁶Delaware Valley Urology, LLC, Voorhees, NJ

⁷ Fox Chase Cancer Center, Philadelphia, PA

⁸ Alaska Clinical Research Center, Anchorage, AK

⁹ Virginia Urology, Richmond, VA

¹⁰ The Urology Center of Colorado, Denver, CO

¹¹ Brigham and Women's Hospital, Boston, MA

¹² Cedars-Sinai Medical Center, Los Angeles, CA

¹³ Spectrum Health Medical Group, Grand Rapids, MI

¹⁴ UT Southwestern Medical Center, Dallas, TX

¹⁵ Huntsman Cancer Hospital, Institute, University of Utah, Salt Lake City, UT

¹⁶ University of Miami Miller, Miami, FL

¹⁷ University of Colorado, Denver Medical Campus, Denver, CO

¹⁸ University of Vermont Medical Center, Burlington, VT

¹⁹ Lancaster Urology, Lancaster, PA

²⁰ Thomas Jefferson University, Philadelphia, PA

²¹ Carolina Urology Partners, Gastonia, NC

Background:

The decision to provide adjuvant therapy to men with high risk pathology after radical prostatectomy (RP) is confounded by tremendous uncertainty. We prospectively evaluated the impact of the Decipher® test (GenomeDx Biosciences Inc., Vancouver), which predicts metastases after RP, on patient and provider decision quality.

Methods

150 adjuvant patients were enrolled by 43 urologists from 19 community and academic practices. Patients with pathologic T3 stage classification (pT3) or positive surgical margins (SM+) after RP were included. Participating physicians provided a management recommendation before and after exposure to Decipher test results. Patients completed validated surveys on health-related quality of life, decisional conflict, and prostate cancer-related anxiety.

Results

Median patient age at RP was 64 years; 67% and 50% had pT3 and SM+ pathology, respectively. Decipher classified 46%, 22% and 32% of men as low-, intermediate- and high-risk, respectively. Pre-Decipher, observation was recommended for 89%. Post-Decipher, 18% (95% CI 12-25%) of treatment recommendations changed, including 9% of low-risk and 31% of high-risk Decipher patients. Patients' Decisional Conflict Scale (DCS) scores decreased (indicating higher decision quality) after exposure to Decipher results (median DCS pre-Decipher 25 [IQR 8-44], median DCS post-Decipher 19 [IQR 2-30], p<0.001), with greatest decreases in the subdomains of decision uncertainty and decision support. Patients with low-risk Decipher results experienced a trend toward decreased prostate cancer-specific anxiety (p=0.13) and a significant reduction in fear of prostate cancer recurrence (p=0.02). Physicians' median DCS scores decreased from 32 [IQR 28-36] to 28 [IQR 12-42] (p<0.001). Decipher results were associated with the decision to pursue ART in multivariable logistic regression (OR 1.48; 95% CI 1.19-1.85, p<0.001).

Conclusions

Observation is the predominantly prescribed management strategy for patients with high risk features at RP. Knowledge of Decipher results was associated with treatment decision-making among these patients: patients at low risk for metastasis had higher rates of observation recommendations and patients at high risk had higher rates of ART recommendations. Decision quality was improved and prostate cancerspecific anxiety was decreased for patients exposed to Decipher results.

This work was supported by GenomeDx Biosciences Inc.

Financial Disclosure:

Emloyees of GenomeDx Biosciences Inc. (Sponsor): Marguerite du Plessis Kasra Yousefi, Maria Santiago-Jimenez Elai Davicioni

No other authors have conflict of interest to report