Decipher Test Impacts Treatment Decision-Making among Patients with Biochemical Recurrence after 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 Clark⁸, Michael Franks⁹, Lawrence Karsh¹⁰, Adam Kibel¹¹, Hyung Kim¹², Brian Lane¹³, Yair Lotan¹⁴, William Lowrance¹⁵, Murugesan Manoharan¹⁶, Paul Maroni¹⁷, Scott Perrapato¹⁸ Paul Sieber¹⁹, Edouard Trabulsi²⁰, Robert Waterhouse²¹, Elai Davicioni², Daniel Lin²

¹University of Washington, Seattle, WA
²GenomeDx Biosciences Inc., Vancouver, BC, Canada
³EMMES Canada, Burnaby, BC, Canada
⁴Lakeland Regional Cancer Center, Lakeland, FL
⁵Urological Research Network; Columbia University Dept of Urology, Miami, FL
⁶Delaware Valley Urology, LLC, Voorhees, NJ
⁷Fox Chase Cancer Center, Philadelphia, PA
⁸Alaska Clinical Research Center, Anchorage, AK
⁹Virginia Urology, Richmond, VA
¹⁰The Urology Center of Colorado, Denver, CO
¹¹Brigham and Women's Hospital, Boston, MA
¹²Cedars-Sinai Medical Center, Los Angeles, CA
¹³Spectrum Health Medical Group, Grand Rapids, MI
¹⁴UT Southwestern Medical Center, Dallas, TX
¹⁵Huntsman Cancer Hospital, Institute, University of Utah, Salt Lake City, UT
¹⁶University of Miami Miller, Miami, FL
¹⁷University of Colorado, Denver Medical Campus, Denver, CO
¹⁸University of Vermont Medical Center, Burlington, VT
¹⁹Lancaster Urology, Lancaster, PA
²⁰Thomas Jefferson University, Philadelphia, PA
²¹Carolina Urology Partners, Gastonia, NC
Background:
Patients and providers have 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 Decipher® test (GenomeDx Biosciences Inc., Vancouver), which predicts metastases after RP, on patient and provider decision quality.

Methods
115 salvage patients were enrolled by 43 urologists from 19 community and academic practices. We included patients with rising PSA after RP. 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 enrollment was 63 years; 43% had pathologic T3 stage classification and 49% had positive surgical margins at RP. Decipher classified 33%, 25%, and 42% as low-, intermediate-, and high-risk, respectively. Pre-Decipher, 58.3%, 32.2% and 9.6% of patients were recommended for observation, SRT, and other treatments, respectively. 32% (95% CI 24-42%) of management recommendations changed post-Decipher, including 18% of Decipher low-risk patients and 50% of Decipher high-risk patients. Patients’ Decisional Conflict Scale (DCS) scores decreased (indicating higher decision quality) after exposure to Decipher test results (median DCS pre-Decipher 27 [IQR 16-41], post-Decipher DCS 23 [IQR 4-30], p<0.001), with greatest decreases in the subdomains of decision uncertainty and decision support. Patients with low-risk Decipher results experienced a significant reduction in general prostate cancer anxiety (p=0.05). Among physicians, median DCS scores decreased from 33 [IQR 26-36] to 29 [IQR 22-34] (p<0.001). Decipher results were associated with the decision to pursue SRT and other treatments in multivariable logistic regression (OR 1.41; 95% CI 1.09-1.81, p=0.01).

Conclusions
Knowledge of Decipher results was associated with treatment decision-making among patients with recurrence after RP. Patients found to be low risk for metastases by Decipher had higher rates of observation recommendations and patients at high risk had higher rates of additional treatment recommendations including SRT. Decision quality was improved and prostate cancer-specific anxiety was decreased among patients considering SRT after RP exposed to Decipher results.

This work was supported by GenomeDx Biosciences Inc.

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

No other authors have conflict of interest to report