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

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Background

- Decision to provide adjuvant therapy to men with high risk pathology after radical prostatectomy (RP) is confounded by tremendous uncertainty.
- Decipher® is a genomic test that was developed to predict disease progression after radical prostatectomy (RP) in a cohort of 359 patients [1].
- Decipher was recently shown to be a valuable tool in the immediate post-RP setting [2].
- However, clinical utility of the Decipher test on adjuvant treatment selection post-RP has not been evaluated in a prospective cohort of patients.

Study Objective

To evaluate the impact of a validated genomic classifier (the Decipher® test) on urologists’ decision-making for adjuvant treatment in a prospective patient cohort with high risk pathology at RP.

Methods

- After providing informed consent, treatment recommendations before and after receiving the Decipher test report as well as Quality of Life (QOL) and Decisional Conflict Scale (DCS) questionnaires were collected.
- The Decipher test results were sent to the ordering physicians and reported the predicted 5-year probability of metastasis after surgery, in addition to clinical characteristics.
- At first, physicians made initial treatment recommendations using clinical variables alone. Physicians then reviewed the Decipher results and we repeated the assessment of treatment recommendations.
- The level of confidence of physicians and patients with regard to treatment recommendations was measured using the Provider Decision Process Assessment Instrument, and the Decisional Conflict Scale respectively [3].
- All statistical tests were two-sided and had a significance level of 0.05. Analyses were performed in R v.3.1 (R Foundation, Vienna, Austria).
- Exact binomial confidence intervals were constructed to measure changes in treatment recommendations, with and without Decipher test results. The paired Wilcoxon test was used to compare continuous measurements of QOL. The McNemar’s test was used to compare QOL and DCS categorical variables.

Conclusions

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

References


Figure 1. Study diagram

Figure 2. Treatment recommendation change by Decipher risk category

Figure 3. Treatment recommendation change by Decipher risk score

Table 1. Patient characteristics in the contemporary cohort

Table 2. Effect of the Decipher test result on urologists treatment recommendations post radical prostatectomy

Table 3. Provider Decision Process Assessment Instrument score or Decision Conflict Scale (DCS) results