

Validation of the Decipher prostate cancer classifier in intermediate to high-risk men treated with radical prostatectomy but without additional therapy upon PSA rise.

**Meeting:**

2015 Genitourinary Cancers Symposium

**Category:**

Genitourinary Cancer

**Subcategory:**

Prostate Cancer - Advanced Disease

**Session Type and Session Title:**

General Poster Session A: Prostate Cancer

**Abstract Number:**

173

**Citation:**

J Clin Oncol 33, 2015 (suppl 7; abstr 173)

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**Background:** Radical prostatectomy (RP) is a primary treatment option for men with intermediate and high risk prostate cancer. Though many will be effectively cured with local therapy alone, these men are by definition at higher risk of adverse pathologic findings and clinical disease recurrence. The Decipher test has been previously shown to predict metastatic progression in cohorts that included adjuvant and salvage therapy after RP. Here we evaluate Decipher in a natural history cohort of at risk men who received no additional treatment until the time of metastatic progression. **Methods:** Men with NCCN intermediate or high risk localized prostate cancer treated with RP at the Johns Hopkins Medical Institute (1992-2010) with at least 5 years of post-operative follow up were identified. Only men with initial undetectable PSA after surgery and who received no therapy prior to metastasis detection were included (n=765). A case-cohort design was used to randomly sample the cohort. The highest Gleason grade cancer tissue was used for RNA extraction and Decipher genomic classifier (GC) scores were calculated with a locked 22-biomarker signature and algorithm. **Results:** GC results were obtained for 260 patients, 28% had positive margins, 77% had EPE, 28% had SVI, 20% had lymph node invasion and 36% had Gleason  $\geq 8$  disease. Median follow up was 9 (IQR 6-12) years and at 15 years post RP the cumulative incidence of BCR, metastasis and prostate cancer specific death was 38%, 21% and 9%. Median GC score was 0.34 (IQR: 0.22-0.52) and was significantly higher among men experiencing metastatic progression during follow up (0.47 vs 0.28 respectively p<0.001). In UVA and MVA (adjusting for clinical covariates), GC had an HR of 1.48 (95% CI: 1.30-1.69, p<0.001) and 1.37 (95% CI: 1.21-1.55, p<0.001) per 10% increase, respectively. **Conclusions:** The majority of the men in this study had excellent long-term outcomes with

surgery alone. Elevated Decipher scores correlated with metastatic events, independent of clinical risk factors. Use of Decipher may allow for selection of candidates for immediate vs. delayed adjuvant or salvage therapy following prostatectomy.

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