

Prospective study of a 17-GENE RT-PCR-based assay for prediction of high risk pathology at radical prostatectomy.

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Background: A biopsy-based 17 gene tissue-based RTPCR assay (Oncotype Dx Genomic Prostate Score, GPS) has been validated in retrospective cohorts as a predictor of adverse pathology and biochemical recurrence in prostate cancer (PCa) patients who underwent radical prostatectomy (RP). The National Comprehensive Cancer Network (NCCN) recommends that men with pathologic Gleason Score (pGS) > 8, pT3+, and/or Lymph Node positive disease (i.e. high risk surgical pathology, HRSP) consider adjuvant therapy after RP. We report herein on GPS at biopsy as a predictor of HRSP in men presenting with clinically low-risk PCa. **Methods:** As part of an ongoing observational study of GPS (N = 1200), we performed an exploratory analysis in men who elected RP as initial disease management. Descriptive statistics were reported. Binary logistic regression was performed to determine the association between GPS and HRSP. The odds ratio (OR) per 20 GPS units and 95% confidence interval (CI) were reported. All analyses were conducted with SAS 9.4. **Results:** Of the 1,200 patients enrolled in the study, 150 (21 sites) selected RP for initial management; 122 (19 sites) had biopsy and surgical pathology data available for analysis. Median age was 63 (range 50-79) years, with 38% > 65 yrs. There were 72 (59%), 39 (32%), and 11 (9%) patients who had NCCN Intermediate-, Low-, and Very Low-Risk disease, respectively Median GPS was 30 (IQR 20-40, range 8-82). Biological risk (GPS+NCCN) differed from NCCN risk in 28 cases (23%). At surgery, 29 /122 (24%) of patients had HRSP; of these, 1 had NCCN Very Low-, 8 had Low-, and 20 had Intermediate-Risk cancer at diagnosis. GPS was a significant predictor of HRSP (OR per 20 GPS units: 2.1; 95% CI: [1.2, 4.0]; p-value 0.02). No other clinical factor was significantly associated with HRSP. GPS remained significant after adjusting for NCCN risk group (OR per 20 GPS units: 2.0; 95% CI 1.1-3.8, p = 0.03). Incorporation of GPS increased the AUC for prediction of HRSP from 0.57 (NCCN alone) to 0.65 (NCCN + GPS) **Conclusions:** GPS derived from biopsy tissue is an independent predictor of HRSP. This information may be valuable in treatment planning for men with clinically low risk PCa who are at risk for HRSP.