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The 17-gene Genomic Prostate Score (GPS) Assay: Initial Clinical Experience of 4,000 Patients

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Introduction and Objectives

The 17-gene GPS assay (Genomic Health Inc., Redwood City, CA) is a biopsy-based gene expression assay that has been clinically validated to predict the likelihood of aggressive prostate cancer (PCa) at time of diagnosis. Here we report the commercial laboratory experience from the first 4,000 patients tested.

Methods

4,000 samples that passed pathology review and RT-PCR quality measures were included. GPS (scale 0-100) was calculated based on the validated algorithm of 12 cancer-related and 5 reference genes. Submitting physicians provided NCCN® clinical risk group classification and samples were centrally reviewed for Gleason score (GS). Descriptive statistics for clinicopathologic variables and Spearman rank correlation (r) between the GPS and variables were calculated.

Results

The mean GPS for the cohort was 24.9 (median 23, range 0-100). 3,161 samples (79.0%) were GS 3+3 (mean GPS 23.1) and 839 samples were GS 3+4 (mean GPS 31.9); r=0.29 (p<0.0001). By age, 449 patients (11.2%) were <55y, 1,680 (42.0%) 55-65y, 1,871 (46.8%) >65y, with a mean GPS of 21.3, 23.4, 27.1; r=0.18 (p<0.0001). Of patients with NCCN risk classification provided (n=3,816), 29.6% (n=1,131) patients were classified as very low, 38.7% (n=1,478) low, and 31.6% (n=1,207) low-intermediate risk, with a mean GPS of 22.1, 23.4, and 29.4; r=0.23 (p<0.0001). 497 samples (12.4%) were <1mm, 418 (10.5%) were 1 mm, 918 (23.0%) 1-2 mm, and 2,167 (54.2%) >2mm, with a mean GPS of 21.0, 21.8, 22.9, and 27.3. Use of the GPS changed risk assessment in 25.2% (963/3,816) of patients with a pre-assigned NCCN risk. Among NCCN low risk patients, GPS changed risk assessment in 48.2% of patients; risk assessment decreased from low to very low in 36.9% and increased from low to low-intermediate in 11.3% of cases.

Conclusions

The GPS results in the first 4,000 biopsy samples displayed a broad range within each GS, age, NCCN risk, and tumor group, indicating a wide spectrum of individual tumor biology within current clinical categories. There was a modest but statistically significant correlation between GPS and GS, age, and NCCN risk category. The risk reclassification by the GPS in this large database is consistent with the results of prior studies. Use of the GPS improved risk stratification for men with newly diagnosed PCa, providing physicians and their patients personalized information to make educated treatment decisions regarding the initial management of their disease.

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