Genomic Prostate Score® Testing Reveals Broad Heterogeneity of Risk Among NCCN® Favorable Intermediate Risk Patients

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Introduction and Objective: Recently-updated National Comprehensive Cancer Network® (NCCN®) Prostate Cancer Guidelines include a subclassification of Intermediate-Risk (IR), termed Favorable-Intermediate Risk (FIR), for whom active surveillance may be considered. FIR patients are distinguished from Low Risk (LR) patients by the presence of one of three IR features: presence of Gleason Score (GS) 3+4 disease, clinical stage T2b/c, or PSA 10-20 ng/ml. This group is thus heterogeneous, and whether all IR features bear equivalently on patient risk is unclear. We evaluated the probability of having adverse pathology as measured by the Oncotype DX Genomic Prostate Score® (GPS) test in a large cohort of FIR patients who submitted biopsies for commercial laboratory testing.

Specific Aims: Assess the frequency of submitted biopsies having adverse pathology, as measured by Oncotype DX Genomic Prostate Score® (GPS) test, to refine the risk classification of a heterogenous FIR patient population.

Rationale and Background: The recently-updated National Comprehensive Cancer Network® (NCCN®) Prostate Cancer Guidelines included a new subclassification of IR, termed FIR. This is a heterogenous group of patients who are assessed based on the presence of numerous histological and staging features. The goal of this study was to determine if Oncotype DX Genomic Prostate Score® (GPS) can aid in further classification of this heterogenous group.

Methods and Materials: Commercial reports for >4900 NCCN® FIR patients tested with the GPS assay between 5/15/2017 and 5/28/2018 were reviewed for GPS result and post-test risk categorization. Methods for score generation and risk group definitions have been described elsewhere.

Results: GPS result spanned the full range (0 to 100), with median score of 27. Overall, 17% and 16% of patients' results placed them in High Risk (HR) and LR, respectively. GS 3+3 patients had 9% HR and 26% LR results; GS 3+4 subset had 20% HR and 13% LR.

Discussion and Conclusion: The wide range of GPS results in this FIR patient subset shows diversity of risk based on tumor biology. Notably, score distributions and resulting risk classification for patients with GS 3+3 and 3+4 disease differ. GPS testing identifies FIR patients whose risk more resembles that of low or high-risk patients, aiding treatment decisions in this heterogeneous group.

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