Molecular classifier testing for newly diagnosed localized prostate cancer in the state of Michigan

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INTRODUCTION AND OBJECTIVES: Tissue-based molecular classifier (MC) tests may assist with management decisions in patients with newly diagnosed prostate cancer (PCa). While retrospective data has supported the validity, there is little published data regarding their real-world use. We sought to determine and compare the current patterns of use of the Decipher Biopsy, Oncotype DX, and Prolaris tests across a diverse, statewide quality improvement collaborative.

METHODS: We analyzed all patients with newly diagnosed PCa who underwent prostate biopsy at one of 44 MUSIC practices, which includes >90% of urology practices in Michigan. We prospectively collected data on the use of three tissue-based MC tests: Decipher Biopsy, Oncotype DX Prostate, and Prolaris. We determined associations between MC use and demographic and clinical data, including age, race, Charlson Comorbidity Index (CCI), Gleason score, and clinical T (cT) stage, as well as variation across practices. Similar analyses were performed in the ″AS-appropriate″ subgroup: those considered candidates for Active Surveillance (AS) based on MUSIC AS Appropriateness Criteria (Gleason 3+3 and low volume Gleason 3+4).

RESULTS: A total of 3,968 men were diagnosed with clinically localized PCa from Jan-Sept 2017, and 727 (18.3%) underwent MC testing with Decipher (n=236), Oncotype DX (n=67), and Prolaris (n=424). 317/727 (43%) of tests were performed on AS-appropriate patients. MC testing was associated with biopsy Gleason grade of 7, lower cT stage, lower prostate specific antigen, and a greater number of CCI (all $p<0.05$). In the AS-appropriate subgroup, MC testing was associated with a Gleason score of 3+4 (vs 3+3), African American race, increasing CCI, and lower cT stage ($p<0.05$). Variability of MC testing among practices ranged from 0% to 93%, with 6 practices performing MC testing on ≥60% and 29 practices performing MC testing on <5% of newly diagnosed patients. In AS-appropriate patients, 111 (35.5%) had MC test results above the test-specific AS threshold. Conversely, of 113 patients with low volume Gleason 3+4 disease, 50 (44.2%) had MC test results below the AS threshold.

CONCLUSIONS: There is variability of MC testing in patients with newly diagnosed localized PCa, and testing is performed in both AS-appropriate and higher risk patients. In AS-appropriate patients, there is greater use of testing in Gleason 3+4 patients, and nearly half of these patients have results supporting potential eligibility for AS. Additional follow-up will help determine whether MC tests may assist with clinical management.