MEDBRIEF

Can Genomic Classifier Tests Influence Prostate Cancer Decisions?

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TOPLINE:

A systematic review found that genomic classifier tests can influence risk assessments and treatment decisions among patients with localized prostate cancer but studies evaluating these tests vary widely in quality, and researchers noted a need for better data on the cost-effectiveness and clinical utility of these tests as well as their impact on racial and ethnic groups, especially Black men.

METHODOLOGY:

- Determining the optimal treatment for patients with prostate cancer remains a challenge. Clinical risk assessment tools for prostate cancer, including those provided by the National Comprehensive Cancer Network, rely on tumor stage, prostate-specific antigen levels, and Gleason grade groups, but have limited predictive accuracy and can lead to overtreatment or undertreatment.
- Genomic classifier tests, such as Decipher, Prolaris, and Oncotype DX Genomic Prostate Score, have been developed to improve the accuracy of risk classification and treatment decisions by evaluating the genetics associated with tumor aggressiveness. Despite their potential, these tests are used inconsistently in clinical practice.
- Researchers conducted a systematic review of 19 studies published between January 2010 and August 2024 to assess the impact genomic classifier tests had on risk classification and first-line treatment decisions in patients with localized prostate cancer. Researchers assessed the risk for bias in the studies as well as test type and population characteristics.
- Decipher was used in four studies, Genomic Prostate Score in 10, and Prolaris in five.

TAKEAWAY:

- A total of 10 studies reported risk reclassifications using genomic classifier testing. In observational studies with a low risk for bias, most patients with very low or low baseline risk maintained their risk category, with some variation by test type: 88.1%-100% with the Genomic Prostate Score, 82.9%-87.2% with Decipher, and 76.9% with Prolaris. One randomized trial,

however, found rates of reclassification to higher risk were more common. In the trial, 34.5% of patients with very low risk and 29.4% with low risk were reclassified to higher risk categories after Genomic Prostate Score testing.

- For patients with baseline intermediate risk, results varied by genomic test. Not many patients in observational Genomic Prostate Score studies reported higher risk reclassification (0%-1.7%) but some reported lower reclassification (3.8%-28.8%), whereas Decipher-based observational studies reported more upward risk reclassification (18.5%-40.5%) and downward reclassifications (34.9%-56.8%), as did Prolaris studies (17.6%-20.8% reclassified as higher risk and 20.8%-33.0% as lower risk).
- Reclassification using genomic classifier testing may vary by race. One study, for instance, found no change in risk for 43% of Black men and 40% of White men, but one third of Black men were reclassified to a lower risk and 24% to a higher risk vs 50% of White men to lower risk and 10% to higher risk.
- On the treatment decision front, 12 observational studies demonstrated that treatment decisions after testing tended to favor active surveillance, with adoption rates varying by risk groups, whereas two randomized trials found that Genomic Prostate Score modestly increased patients' preference for prostatectomy or radiation.

IN PRACTICE:

Although genomic classifier tests can affect risk reclassification and treatment choice, different findings in observational studies and randomized trials across different tests and baseline risk levels "complicate understanding of the role of these tests for patient care," the authors explained "Ultimately, findings from this review alone should not drive changes in clinical practice. Other factors, such as the ability of [genomic classifier] tests to predict oncologic outcomes and the cost-effectiveness of these tests, must also be considered."

In an editorial, experts agreed that these tests hold promise but the current evidence for genomic classifiers as predictive biomarkers "remains limited." For instance, "it is not established whether [genomic classifier]-based reclassification to a lower risk category resulting in [active surveillance] or using genomic classifiers to decide adjunct therapies, such as ADT [t androgen deprivation therapy], for intermediate- or high-risk patients improves clinical outcomes," the editorialists wrote.

SOURCE:

This study, led by Amir Alishahi Tabriz, MD, PhD, MPH, Department of Health Outcomes and Behavior, Moffitt Cancer Center in Tampa, Florida, was published online on January 21 in *Annals of Internal Medicine* alongside an editorial.

LIMITATIONS:

Many of the included studies received support from test developers, potentially introducing bias. Significant variations in screening patterns, risk determination cutoffs, and differences in pathology and clinical practices were observed across studies. Additionally, reliance on observational methods limited the ability to establish causality between genomic classifier results and subsequent risk reclassification and treatment decisions.

DISCLOSURES:

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