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Screening for PSA Velocity Leads to Many Unnecessary Biopsies and Should Be Removed from Screening Guidelines

Researchers at Memorial Sloan Kettering Cancer Center have found that change in PSA levels over time — known as PSA velocity — is a poor predictor of prostate cancer and may lead to many unnecessary biopsies. The new study of more than 5,000 men was published online February 24 in the Journal of the National Cancer Institute. Andrew Vickers, PhD, Associate Attending Research Methodologist in the Department of Epidemiology and Biostatistics and lead author said, "We have found no evidence to support the recommendation that men with a high PSA velocity should be biopsied in the absence of other indications. In other words, if a man's PSA has risen rapidly in recent years, there is no cause for concern if his total PSA level is still low and his clinical exam is normal."

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Andrew Vickers, PhD, lead author of the study and Associate Attending Research Methodologist in the Department of Epidemiology and Biostatistics

Prostate cancer is the most common cancer among American men and the second leading cause of cancer deaths in men, according to the American Cancer Society. While PSA screening is widely used for the early detection of prostate cancer, it is also associated with a high rate of overdiagnosis, which can lead to unnecessary treatment and anxiety. Currently, early detection guidelines of several organizations (the National Cancer Center Network and the American Urological Association) recommend that men with a rapid rise in PSA — or a high PSA velocity — have a surgical biopsy for prostate cancer, even if there are no other indicators that cancer may exist. Those indicators could be an elevated baseline PSA or a positive digital rectal exam (DRE).

This study's population came from the Prostate Cancer Prevention Trial. Five thousand five hundred and nineteen men aged 55 years and older with no previous prostate cancer diagnosis, normal DRE, and a baseline PSA of 3.0 ng/mL or less were randomly assigned to finasteride — a drug commonly used to treat enlargement of the prostate gland, more commonly referred to as BPH, or benign prostatic hypertrophy — or placebo for seven years. This particular study focused on the men in the placebo group. The men were followed with yearly PSA tests, with biopsy recommended for men with a PSA higher than 4.0 ng/mL. After seven years, all men who were not diagnosed with prostate cancer were asked to consent to an end-of-study biopsy.

Dr. Vickers and colleagues found no important association between PSA velocity and biopsy outcome after adjusting for risk factors such as age, race, and PSA levels. PSA alone was a much better predictor of biopsy outcome than PSA velocity.

According to Peter T. Scardino, MD, Chair of the Department of Surgery, "This study should change practice. We have previously published papers determining that PSA naturally varies from month to month and have urged men whose PSA suddenly rises to wait six weeks and repeat the test before agreeing to a needle biopsy. This new study in a large population of men provides even stronger evidence that using changes in PSA as a basis for recommendation for biopsy leads to many more unnecessary biopsies and does not help to find the more aggressive cancers that we want to find and treat." Dr. Scardino added that "men should be cautious before rushing into a biopsy for minor variations in their PSA level."

The work was funded by the Prostate Cancer Foundation, the <u>Sidney Kimmel Center for Prostate and Urologic Cancers</u>, and a P50-CA92629 SPORE grant from the <u>National Cancer Institute</u> to Dr. Scardino. Additional support was obtained from the National Institutes of Health.

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