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Landmark Stockholm3 North American clinical trial presented at ASCO-GU

The primary results of the landmark SEPTA trial, with over 2,000 racially and ethnically diverse biopsied men recruited in the US and Canada, were presented by Professor Scott Eggener at the ASCO-GU (The American Society of Clinical Oncology – Genitourinary Cancer Symposium) conference in San Francisco on January 26. The study found that use of the blood-based biomarker Stockholm3 was more accurate and could avoid up to half of unnecessary biopsies compared to current clinical practice. The findings were similar across all racial and ethnic groups.

"Stockholm3 showed proof of non-inferior sensitivity while simultaneously having a dramatically improved specificity compared to PSA," Dr. Eggener said in his presentation.

Stockholm3, which incorporates plasma proteins, a polygenetic risk score and clinical variables was developed by researchers at the Karolinska Institute in Sweden. More than 90,000 men have been included in clinical studies and the test is being used in clinical care in multiple European countries. The SEPTA trial was carried out at 17 US and Canadian sites and is the first prostate cancer trial where the majority are from historically underrepresented minorities. Out of 2,129 recruited men 1,160 were either Asian, Black or Hispanic.

Prostate cancer is the most common form of cancer in American men. In 2024, it is estimated that 300,000 men will be diagnosed with, and 35,000 will die from, prostate cancer in the United States (1). Early detection and reduced overdiagnosis are crucial for improved treatment outcomes, decreased mortality, and better use of healthcare resources.

"Stockholm3 could have a significant impact on risk stratification of prostate cancer in the diverse American population, while minimizing unnecessary diagnosis and treatment of indolent cancers and potentially redefine the current standard of care," says David Rosén, CEO A3P Biomedical.

(1) Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. CA Cancer J Clin. 2024 Jan-Feb; 74(1): 12-49. doi: 10.3322/caac.21820. Epub 2024 Jan 17. PMID: 38230766.

Online link to SEPTA trial: https://meetings.asco.org/abstracts-presentations/230554

The American Society of Clinical Oncology – Genitourinary Cancer Symposium features the latest high-impact science, multidisciplinary expertise, and evidence-based practices in GU cancer care and took place from January 25-27, 2024, in San Francisco, USA.



Scott Eggener, MD

Professor of Surgery and Radiology, Vice Chair of Urology, Director High Risk and Advanced Prostate Cancer Clinic, University of Chicago

Dr. Scott Eggener is a urologic oncologist with extensive clinical and research expertise in prostate cancer and is co-director of the UChicago Medicine High-Risk and Advanced Prostate Cancer Clinic (UCHAP), a program that provides focused care for men at high risk for developing prostate cancer and those with advanced disease.

His research — which has resulted in over 300 publications — exclusively focuses on urologic cancers and primarily focuses on improving the screening, imaging and treatment of men with prostate cancer. Dr. Eggener has been an associate editor at four medical journals, is on the executive board of International Volunteers in Urology and has chaired or participated in multiple ASCO/AUA/NCCN cancer guideline panels.

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About A3P Biomedical

A3P Biomedical's mission is to improve quality of life of men by radically increasing the precision in prostate cancer diagnostics. The company's lead product is Stockholm3, a blood test for early detection of aggressive prostate cancer. Stockholm3 has been developed by scientists at Karolinska Institutet and validated in clinical studies including more than 90,000 men. A3P Biomedical is headquartered in Stockholm, Sweden. For more information, please visit www.a3p.com



About Stockholm3

Stockholm3 is a blood test that combines protein biomarkers, genetic biomarkers, clinical data, and a proprietary algorithm, to predict the risk of aggressive prostate cancer at an early stage. In clinical practice, Stockholm3 finds 100 percent more aggressive prostate cancers and reduces unnecessary biopsies by 50 percent compared to current practice with PSA (1).

Stockholm3 has been evaluated in clinical studies with more than 90,000 men. Data from the latest pivotal study, a randomized study including 12,750 men, was published in The Lancet Oncology in 2021. The study was also awarded the European Association of Urology (EAU) "Prostate Cancer Research Award 2022". Multiple additional studies have been published in high-impact journals, including a previous study with 58,000 men, published in The Lancet Oncology in 2015 (1).

Based on robust peer-reviewed clinical data, leading Nordic healthcare providers have replaced PSA with Stockholm3. Region Värmland in Sweden has introduced general screening for prostate cancer with the help of Stockholm3 for men in the age category 50-75, who benefit from a more precise test with increased sensitivity and specificity. At the same time, healthcare providers can reduce direct costs by 17 to 28 percent (1).

(1) Publications, results and clinical validation.

About prostate cancer

Prostate cancer is the second most common male cancer, and the fifth leading cause of cancer related death in men worldwide. According to WHO, 1.4 million men were diagnosed with prostate cancer and 375,000 deaths were reported in 2020. Incidence of prostate cancer is expected to increase by 70 percent until 2040, driven by an aging population.

Attachments

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