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Prostate Health Index - Precision biomarker for prostate cancer diagnosis：Taiwan 2025 update

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According to a 2020 statistic from the New England Journal of Medicine, compared to the early years of prostate-specific antigen (PSA) testing in 1990, the mortality rate for prostate cancer (PCa) in the United States decreased by 51% in 2010. Unfortunately, PSA is not a specific antigen for PCa or clinically significant PCa (csPCa, which refers to high-grade malignancies), resulting in many unnecessary biopsies, especially in cases with a low to medium PSA level of 4–10 ng/ml. Finding more precise diagnostic methods for PCa/csPCa is a globally significant area of research. There are two methods that are recommended by both the United States and the European Union, which significantly increase the accuracy of PCa/csPCa diagnosis: the Prostate Health Index (PHI), a blood marker, and multiparametric Magnetic Resonance Imaging (mpMRI). This presentation focuses on introducing the Prostate Health Index (PHI).

PHI is a mathematical formula that simultaneously considers total PSA, free PSA, and p2PSA—three PSA-related proteins—[(p2PSA/fPSA) x √tPSA]. Since 2010, there have been numerous studies on PHI, and although the numbers vary slightly, the results consistently show that PHI has much greater diagnostic accuracy for PCa/csPCa than traditional tPSA. A 2019 study published in European Urology, comparing 2,488 people from Europe and Asia, found that when PSA was between 2–10 ng/ml, the positive biopsy rates for PCa were only 52% and 13% for Europeans and

Asians, respectively, and even lower for csPCa, with rates of only 23% and 6%. By categorizing patients with PSA levels of 2–10 ng/ml according to their PHI levels, a clear distinction was found: for Europeans, those with PHI ≥ 35 had a 2.2/7.3 times higher positive biopsy rate for PCa/csPCa compared to those with PHI < 35, while Asians had a 4.7/8.6 times higher positive biopsy rate. In both populations, unnecessary biopsies could be reduced by 33% for Europeans and 71% for Asians. The conclusion was as follows: 1. The standards should be different for Europeans and Asians; 2. Regardless of the population, using PHI as a second reference for determining whether a biopsy is needed significantly improves diagnostic accuracy and reduces unnecessary biopsies, especially for Asians with lower PCa/csPCa risk.

In 2012, the U.S. Food and Drug Administration (FDA) officially approved PHI as a second reference for deciding whether to undergo a prostate biopsy when tPSA is between 4–10 ng/ml. PHI was introduced in Taiwan in 2017 (with an out-of-pocket cost of around 2,500 NTD), and in December 2024, it was finally approved for National Health Insurance reimbursement for one PHI test per year when PSA is between 4–10 ng/ml, aiming to improve the accuracy of biopsies and reduce unnecessary biopsies.