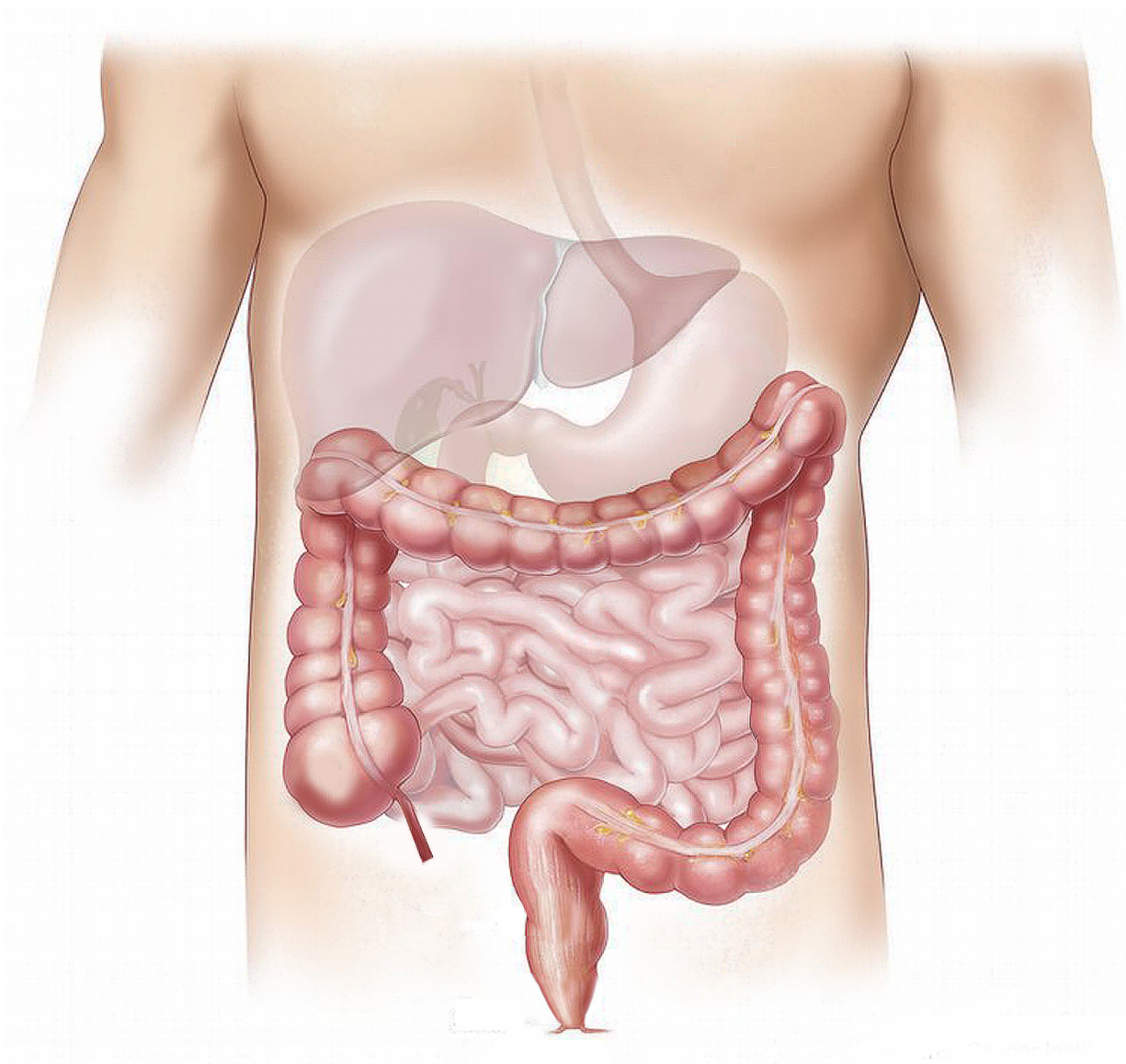


Results of early-stage liver cancer detection using liquid biopsy published

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Today, *Proceedings of the National Academy of Sciences (PNAS)* published the results of a pilot study for early detection of liver cancer in a cohort of HBV carriers at risk for developing the disease. This screening technology, known as HCCscreen, relies on detecting a combination of tumor-specific mutations in cell free DNA (cfDNA) and protein markers. This work was a collaborative effort between National Cancer Center/ Cancer Hospital, Chinese Academy of Medical Sciences and Genetron Health (Beijing) Co. Ltd (Genetron). Based on these promising results, assays such as this, after rigorous clinical validation, could be developed into an application for the detection of early-stage liver cancer.

The HCCscreen assay developed in the study uses both specific mutation profiles from plasma cfDNA along with protein biomarkers. The combination of these markers enabled excellent performance of the assay in a cohort of asymptomatic HBV carriers. A total of 331 HBV carriers (with normal alpha-fetoprotein levels and normal ultrasound) were tested using HCCscreen. Among them, 24 subjects were identified as positive and 307 (out of 331) as negative.

Furthermore, four out of the 24 individuals with a positive HCCscreen test were later diagnosed as having early stage liver [cancer](#) (less than 3 cm) within six to eight months. The early detection with HCCscreen allows earlier intervention with surgery, which significantly increases the likelihood of cure. On the other hand, none of HCCscreen-negative individuals were diagnosed clinically with [liver cancer](#) in the same follow-up period. Therefore, at the time point, this result demonstrated a 17 percent positive predictive value, a 100 percent sensitivity and a 94 percent specificity in this cohort.

One of HCCscreen's core technologies is Mutation Capsule, invented by

Genetron, which enables the accurate detection of hot spot mutations, indels and hepatitis B virus (HBV) integrations commonly present in HCC tumors. Besides the biomarkers described in this study, this assay can be further optimized to detect more genetic alterations, such as copy number variations. The optimized assay has been validated in additional cohorts with >93 percent sensitivity and >98 percent specificity.

Mr. Sizhen Wang, co-founder and CEO of Genetron, emphasized: "Some developed countries have achieved extraordinary performance in reducing morbidity and mortality of some cancer types, such as colorectal cancer in the United States and gastric cancer in Japan, which need to thank the efficient early screening of the cancers. Genetron is working diligently and would like to launch the product for early screening of liver cancer, therefore, to reduce mortality of liver cancer patients. The similar technology can be adapted and developed to screen other types of cancers after clinical validation, and we are dedicated to providing effective technologies for the early detection of cancer in high-risk populations, as well as in general populations."

With a noninvasive blood test, the liquid biopsy technology can provide important diagnostic indicators for asymptomatic HBV carriers. The research team is currently conducting a larger scale clinical trial to further improve and validate the method.

Background

Liquid biopsy using plasma cell free DNA (cfDNA) mutation profiles has made great progress in recent years, and promising results have been demonstrated in early screening of multiple cancer types.

Patients identified by HCCscreen as being positive for tumor-specific markers in this prospective study were mostly asymptomatic as they had very early stage liver cancer. Compared to the differentiation of healthy

individuals and hospitalized cancer patients in retrospective studies, it could be more challenging to distinguish asymptomatic early-stage HCC patients from at-risk individuals, however, the prospective studies could be important to set up the algorithm and threshold with favorable performance in the screening of early HCC, as the screening of HCC most likely happens in the context of high-risk individuals in clinical practice.

More information: Chunfeng Qu et al, Detection of early-stage hepatocellular carcinoma in asymptomatic HBsAg-seropositive individuals by liquid biopsy, *Proceedings of the National Academy of Sciences* (2019). [DOI: 10.1073/pnas.1819799116](https://doi.org/10.1073/pnas.1819799116)

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