New Blood Test IDs Numerous Cancers With 76% Accuracy

The test was able to identify many cancers, and their location, at early stages.

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A new single blood test from the biotechnology company GRAIL has demonstrated considerable precision at identifying numerous types of cancers and can even identify some malignancies, along with their locations, during early stages, when they are easier to treat.

Researchers presented findings at the American Society of Clinical Oncology (ASCO) annual meeting from the ongoing prospective, multicenter observational Circulating Cell-free Genome Atlas (CCGA) study of the company's early detection blood test. Known as an optimized targeted methylization assay, the test analyzes circulating DNA from cancer cells. Such tests are sometimes called liquid biopsies because they may be able to replace some surgical tissue biopsies.

This analysis included a subset of 2,301 people out of approximately 4,500 participants in the larger study: 1,422 people who had previously been diagnosed with more than 20 types of cancer across all stages as well as 879 participants who had not previously been diagnosed with cancer. The study will collect follow-up data for five years.

The study conducted several analyses of the test's effectiveness by looking only at 12 pre-specified deadly cancer types, including anal/rectal, colorectal, esophageal, gastric, head and neck, liver, lung, ovarian and pancreatic cancers and hormone receptor–negative breast cancer as well as multiple myeloma and other blood cancers; 63% of all cancers in the United States fall into these categories.

The blood test's sensitivity, or its ability to accurately identify cancer when it is present, for the 12 cancer types analyzed in the study was 76% overall. For the 12 deadly cancers combined, the sensitivity was 34% for Stage I malignancies , 77% for Stage II, 84% for Stage III and 92% for Stage IV. Considering Stages I though III together, the sensitivity was 69% overall and ranged from 59% for lung cancer to 86% for head and neck cancer. When one of the 12 types of deadly cancer was identified, the test correctly identified a tissue of origin 84% to 92% of the time. (This analysis excludes leukemias, which are not staged.)

Looking at a broader selection of more than 20 cancer types—representing 97% of all newly diagnosed cancers in the National Cancer Institute's surveillance database—the test's sensitivity

was 55% (784 cases out of 1,422). For those 784 cases, the test identified a tissue of origin in 94% of cases; within that group, the test correctly identified the tissue of origin in 90% of cases.

The test's specificity, or its ability to correctly rule out cancer if it was not present, was 99% for all cancers. In other words, the test had a false positive rate of 1%.

"These very promising data indicate that a highly specific blood test for early cancer detection is approaching reality," Minetta Liu, MD, of the Mayo Clinic, the lead investigator on the CCGA study, said in a GRAIL press release.

One challenge in developing liquid biopsy tests is to avoid diagnosing many early, slow-growing cancers that likely never would progress to clinically significant disease.

"When we set out on this journey, we knew that to be successful, a blood-based screening tool would need to detect the clinically important cancers and not contribute to overdiagnosis of indolent cancers at the earliest stages," said GRAIL founder and director Rick Klausner, MD. "Data being presented at ASCO suggest GRAIL's test preferentially detects the most lethal cancers and can detect tumors when they are still localized and amenable to successful treatment."

This training phase of the study was designed to optimize the DNA test. GRAIL now plans to evaluate the accuracy of the diagnostic test in more than 100,000 people not yet diagnosed with cancer.

To read the conference abstract, click here.

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