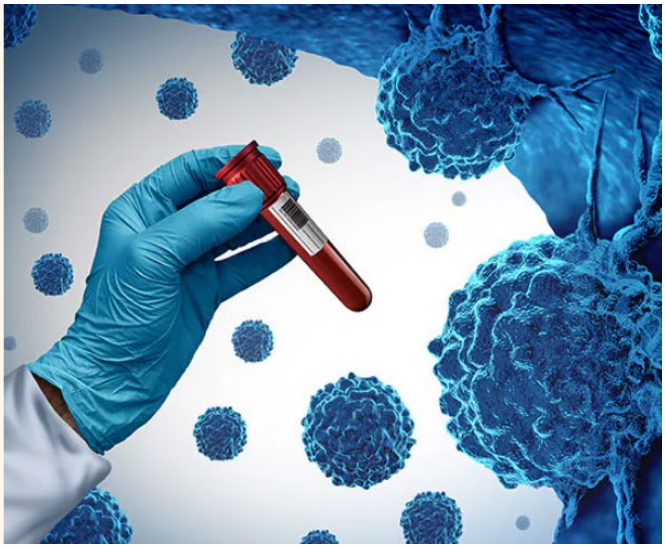
HEALTH

The blood test has high accuracy in detecting colon cancer

germanic news March 18, 2024 No Comments



A cell-free DNA (cfDNA) blood test designed to detect abnormal DNA signals in people at average risk of colorectal cancer (CRC) correctly detected colorectal cancer in most people with confirmed disease, according to a new study.

The cfDNA blood test had a sensitivity of 83% for CRC, a specificity of 90% for advanced neoplasms, and a sensitivity of 13% for advanced precancerous lesions. Other noninvasive screening methods have a sensitivity of 67% to 94% for colorectal cancer and 22% to 43% for advanced precancerous lesions.

"The study results are a promising step toward developing more convenient tools to detect colorectal cancer early while making it easier to treat," said senior author William Grady, MD, medical director of the Gastrointestinal Cancer Prevention Program at the Fred Hutchinson Cancer Center in Seattle, Washington.

"The test, which has similar accuracy in detecting colorectal cancer as stool tests for early detection of cancer, could provide an alternative for patients who might otherwise reject current screening options," he said.

The study was published online March 14 *in The New England Journal of Medicine*.

Analysis of the accuracy of the blood test

Grady and colleagues conducted a multisite clinical trial called ECLIPSE that compared the sensitivity and specificity of a cfDNA blood test (Shield, Guardant Health) to those performed with colonoscopy, the gold standard for colorectal cancer screening became. Guardant led and funded the study.

The Guardant's Shield test is designed to detect CRC based on genomic alterations, aberrant methylation status and fragmentomic patterns, which are displayed as an "abnormal signal detected" result. Similar blood tests are being developed as “liquid biopsy” tests for other emerging cancer screening tests.

The study included 7,861 people at average risk of colorectal cancer who underwent routine screening with colonoscopy at 265 sites across the United States, including primary care and endoscopy centers in academic and community settings. Eligible individuals were between 45 and 84 years old (mean age 60 years) and 53.7% were women. The racial and ethnic characteristics of participants largely reflected the demographic distribution in the 2020 U.S. Census.

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Overall, 54 of 65 (83.1%) participants with colorectal cancer detected by colonoscopy had a positive cfDNA blood test. However, 11 participants (16.9%) with CRC had a negative test.

The cfDNA blood test identified 42 of 48 stage I, II, or III colorectal cancers, providing a sensitivity of 87.5%, including 65% for stage I cancers, 100% for stage II cancers, and 100% for stage II cancers III. The test also identified all 10 stage IV CRC cases. There were no significant differences in susceptibility for CRC based on location of the primary tumor, histologic grade of the tumor, or demographic characteristics.

Of participants without advanced colorectal neoplasia at colonoscopy, 89.6% had a negative cfDNA blood test and 10.4% had a positive test.

In those with a negative colonoscopy – no colorectal cancer, advanced precancerous lesions, or non-advanced precancerous lesions – the specificity was 89.9%.

Among 1116 participants with advanced precancerous lesions identified as the most advanced lesion at colonoscopy, the cfDNA blood test was positive in 147, indicating a sensitivity for advanced precancerous lesions of 13.2%.

Although the blood test has similar sensitivity to stool-based tests for colorectal cancer, its accuracy is lower than colonoscopy, which remains the current gold standard for colorectal cancer screening, Grady said.

“Colon cancer is common and highly preventable through screening, but only about 50 to 60% of people eligible for screening take these tests,” he said. “Getting people to get screened for cancer works best when we offer them screening options and then let them decide what works best for them.”

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Future research

Colorectal cancer is the second leading cause of cancer death among adults in the U.S. and is now the third most commonly diagnosed cancer in people under 50, Grady said. Although

overall CRC death rates have fallen in recent years, rates among those under 55 have increased since the mid-2000s.

“When colorectal cancer is detected earlier and the cancer has not yet spread throughout the body, the outcomes for patients are much better, reflected in a much better 5-year survival rate. “It makes sense that an effective blood-based test could have a potential role, especially for those who are not already being screened,” said Joshua Melson, MD, clinical professor of medicine and director of the High-Risk Gastrointestinal Cancer Clinic at the Cancer Center the University of Arizona in Tucson.

Melson, who was not involved in this study, noted that blood-based tests show promise for cancer detection but need additional support for practical implementation. For example, the Shield blood test has difficulty detecting precancerous lesions, and it remains unclear what the optimal intervals for repeat testing after a negative test would be, he said. In addition, screening programs must ensure that they are able to deal effectively with a positive test result.

“For a screening program to actually work, these patients must undergo a follow-up colonoscopy if a noninvasive test (whether blood or stool-based) is positive,” he said.

Proper communication with patients will also be important, said Gloria Coronado, PhD, associate director of population sciences at the University of Arizona Cancer Center. Coronado, who was not involved in this study, has developed colorectal cancer screening messages for specific patient populations and studied patients' responses to colorectal cancer blood tests.

In a study by Coronado and colleagues of more than 2,000 patients who passively refused a stool test and had an upcoming clinic visit, CRC screening rates were 17.5 percentage points higher in the group offered the blood test than in the group Group that received usual care. In qualitative interviews, one patient said of the blood-based testing option, “I screamed hallelujah!”

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“Patients believed that a blood test was more accurate than a stool test. However, the opposite is true for detecting advanced adenomas,” she said. “It will be important to balance the high acceptance and enthusiasm for the blood test with the lower performance of the blood test compared to other tests already on the market.”

In a statement accompanying the study's release, the American Gastroenterological Association welcomed these results as an exciting development but cautioned that a blood-based test is not interchangeable with a colonoscopy.

“The Centers for Medicare and Medicaid Services (CMS) has decided to adopt a blood test for colorectal cancer screening every three years if the test achieves 74% sensitivity for colorectal cancer, 90% specificity, and FDA approval,” it said in the statement. “However, a blood test that only meets CMS criteria is inferior to currently recommended tests and should not be recommended as a replacement for current tests. Such a test could be recommended for patients who refuse all other recommended tests because any screening is better than no screening at all.”

The study was funded by Guardant Health. Grady is a paid member of Guardant's Scientific Advisory Board and advised on the design and procedures of the clinical trial and data analysis. Melson previously worked as a consultant for Guardant. Coronado reported no relevant disclosures.

Carolyn Crist is a health and medical journalist who covers the latest studies for Medscape, MDedge and WebMD.

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