Clinical study of a blood test shows 83% accuracy for detecting colorectal cancer

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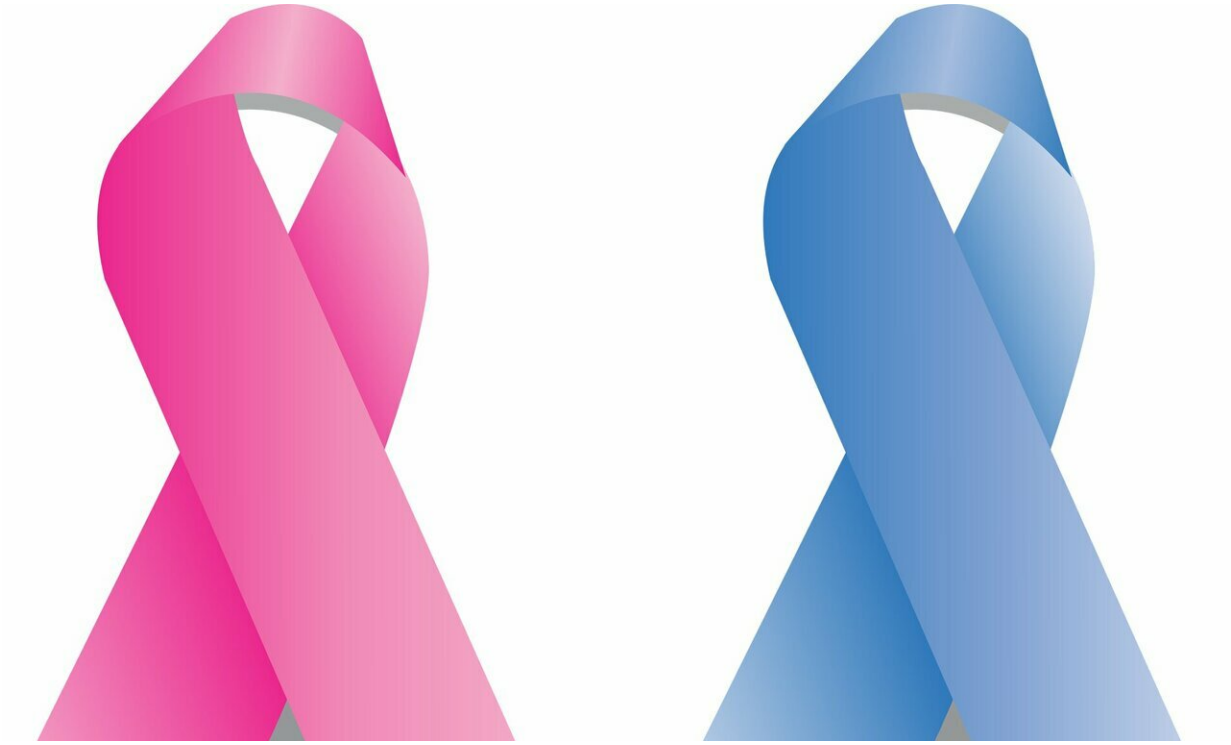

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A blood test intended for screening for colorectal cancer in people who are of average risk and not experiencing symptoms correctly detected colorectal cancer in 83% of people confirmed to have the disease, according to a study published March 14 in the *New England Journal of Medicine*.

The accuracy rate for colorectal cancer is similar to at-home stool tests used for early detection of colorectal cancer.

"The results of the study are a promising step toward developing more convenient tools to detect colorectal cancer early while it is more easily treated," said corresponding author William M. Grady, MD, a gastroenterologist at Fred Hutchinson Cancer Center. "The test, which has an accuracy rate for colon cancer detection similar to stool tests used for early detection of cancer, could offer an alternative for patients who may otherwise decline current screening options."

The findings come from the ECLIPSE study, a multisite clinical trial of nearly 8,000 people ages 45 to 84 led by Guardant Health. The ECLIPSE study compared Guardant's Shield blood test to colonoscopy, which is the current gold standard for colorectal cancer screening.

The Shield test detects colorectal cancer signals in the blood from DNA that is shed by tumors, which is called circulating tumor DNA (ctDNA). ctDNA is also being used in "liquid biopsy" tests used for monitoring for cancer recurrence in people who have been treated for cancer and for other emerging cancer screening tests.

Of the 7,861 people included in the *NEJM* report, 83.1% of the participants with colorectal cancer confirmed by colonoscopy had a positive blood test for ctDNA and 16.9% had a negative test—in which a colonoscopy showed colorectal cancer but the ctDNA test did not. The test was most sensitive for colorectal cancers, including early stage cancers, and was less sensitive for advanced precancerous lesions, which can turn into cancer over time.

Grady said that the sensitivity of the blood test for colorectal cancer is similar to stool-based tests and lower than that of colonoscopy, which he still considers the most accurate screening test for colorectal cancer.

"Colorectal cancer is common and very preventable with screening, but only about 50% to 60% of people who are eligible for screening actually take those tests," said Grady, who is the medical director of Fred Hutch's Gastrointestinal Cancer Prevention Program. "Getting people to be screened for cancer works best when we offer them screening options and then let them choose what works best for them."

According to the American Cancer Society, colorectal cancer is the second most common cause of cancer deaths in adults in the U.S. and is expected to account for 53,010 deaths in 2024. While death rates from colorectal cancer in older adults has declined, rates among those under age 55 have increased by about 1% a year since the mid-2000s. Current guidelines advise that people of average risk for colorectal cancer begin regular screening at age 45.

"We continue to see younger people getting colorectal cancer and it's now the third most common cancer for people under the age of 50," Grady said. "Having a blood-based test for people to take during routine doctor's visits could be an opportunity to help more people be screened."

More information: A Cell-free DNA Blood-Based Test for Colorectal Cancer Screening, *New England Journal of Medicine* (2024). DOI: 10.1056/NEJMoa2304714

Provided by Fred Hutchinson Cancer Center

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