

Small study supports new stool-based colon cancer test

April 19 2016



(HealthDay)—A new, but small, study finds more evidence that a

recently approved, stool-based colon cancer test may be effective for certain patients.

Still, experts who looked at the findings stressed that the [test](#), called Cologuard, should never be used as a substitute for the "gold standard" colon cancer test, [colonoscopy](#).

Cologuard is a noninvasive stool DNA test that detects red blood cells and certain DNA mutations that are associated with colon cancer. The test was approved by the U.S. Food and Drug Administration in 2014.

The new study included nearly 400 people at average risk for colon cancer, meaning they had no symptoms and no personal or family history of the disease or precancerous polyps. The [patients](#) had also not yet undergone more invasive screening procedures, such as colonoscopy.

At one year of follow-up, 51 of the patients (about 15 percent) had a positive result on the Cologuard test and were referred for colonoscopy, said a team led by Dr. Mark Prince of USMD Physician Services, a health system based in Dallas.

Of the 46 patients who received a follow-up colonoscopy, four were diagnosed with a colon cancer, 21 with advanced polyps (indicating a heightened risk for the cancer), and nine with non-advanced polyps.

The findings were to be presented Tuesday at the annual meeting of the American Academy for Cancer Research (AACR), in New Orleans. Research presented at meetings should be viewed as preliminary until published in a peer-reviewed journal.

"Colon cancer screening saves lives," Prince said in an AACR news release. "Colonoscopy is the best form of [colon cancer screening](#), but for patients who will not have a colonoscopy, a noninvasive screening test

like Cologuard is needed."

However, "despite the availability of various colon [cancer screening](#) options, more than 40 percent of Americans are not getting screened," he added. "This study highlights the opportunity to expand the screening population by offering new, patient-friendly methods."

Prince is also a speaker for Exact Sciences Corp., the Wisconsin-based maker of Cologuard.

Two experts in colon cancer care agreed with Prince that colonoscopy remains the tried-and-true method of spotting [colon cancer](#). And they believe the new research has its flaws.

"The study lacks a true evaluation of the benefit of this test as their patient selection is quite limited [46 patients]," said Dr. Jules Garbus, a colorectal surgeon at Winthrop-University Hospital in Mineola, N.Y.

He believes that while the Cologuard test may be a welcome addition to screening, colonoscopy "remains the gold standard in the prevention of colorectal cancer."

Dr. David Bernstein is chief of hepatology at Northwell Health in Manhasset, N.Y. He pointed to the results of a recent study in the *New England Journal of Medicine* that found that the Cologuard test had only a 42 percent sensitivity—meaning that it could only accurately spot a precancerous growth less than half of the time.

"The sensitivity of the test, in particular for precancerous polyps, is unacceptably low," Bernstein said, and "Cologuard should not be used as a substitute for colonoscopy when the better test, colonoscopy, is available."

Bernstein also reiterated that the study size of just 46 patients is too low to come to firm conclusions about Cologuard.

"In addition, not all colon cancers have the predetermined DNA mutations measured by Cologuard," Bernstein said, "meaning that other cancers may be missed by this test and we do not know the false-negative rate of Cologuard."

More information: The U.S. National Cancer Institute has more on [colon cancer screening](#).

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Citation: Small study supports new stool-based colon cancer test (2016, April 19) retrieved 6 May 2024 from <https://medicalxpress.com/news/2016-04-small-stool-based-colon-cancer.html>

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