Liquid Biopsy Test Shows Promise for Detecting Early-Stage Colorectal Cancer

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Expert Perspective
“Screening for colorectal cancer can be life-saving, but Americans still lag behind Federal government screening goals because current screening options can be inconvenient and uncomfortable for patients. Though this research needs more investigation, a simple, accurate blood test could help increase screening rates, which could ultimately improve detection of colorectal cancers at earlier stages when treatment is most likely to be curative,” said Nancy Baxter, MD, ASCO Expert in gastrointestinal cancers.

ALEXANDRIA, Va. – A new study has found that a test that identifies circulating tumor cells (CTCs) present in the bloodstream can detect colorectal cancer at an early stage, with accuracy ranging from 84 to 88%. Most prior studies using CTCs have been able to detect late-stage colorectal cancer, and this study is one of the first clinical studies to show that CTCs can be useful for detecting early, more treatable stages of the cancer. These findings will be presented at the upcoming 2018 Gastrointestinal Cancers Symposium in San Francisco, California.

CTCs break away from the primary tumor and travel into the bloodstream where they can then form new tumors at distant locations. Collection of CTCs from the blood is one form of “liquid biopsy.”

“Our study is important because there is still some reticence among patients to use stool-based tests or have an invasive exam like colonoscopy to detect colorectal cancer,” said lead study author Wen-Sy Tsai, MD, PhD, assistant professor, Linkou Chang Gung Memorial Hospital, Taipei, Taiwan. “Our results may point to a solution for people who are reluctant to get an initial screening colonoscopy or are not compliant in returning stool-based test kits that they get from their doctors.”

About the Study
This study was conducted at Chang Gung Memorial Hospital, Taoyuan, Taiwan. The researchers enrolled 620 people over the age of 20 who were coming to the hospital for routine colonoscopies or had a confirmed colorectal cancer diagnosis. Based on the colonoscopy and biopsy, 438 people were found to have either adenomatous polyps (pre-cancerous growths) or early to late-stage colorectal cancers. The remaining study participants had no signs of a pre-cancerous growth or colorectal cancer (comparison group).

All 620 enrollees had 2 milliliters (about half a teaspoon) of blood tested for CTC analysis through a routine blood draw.

The blood samples were processed using CMx, an assay that captures rare CTCs -- such as those found in early-stage cancer -- on a lipid-coated chip that mimics human tissue. The results of these assays were then compared in a blinded analysis with the colonoscopy results.

In prior studies, this assay was found to be able to detect very small numbers of CTCs, even down to the level of one CTC per billion blood cells found in most polyps.

**Key Findings**

The researchers focused on specificity of the liquid biopsy test, which is the proportion of healthy individuals correctly identified as not having polyps or cancer. “We believe our high specificity results are important because a high number of false-positive results would discourage many people who are considering getting screened for colorectal cancer from doing so,” said Tsai. The specificity values were 97.3%, indicating a very low (less than 3%) probability of a false-positive result.

The study results showed that sensitivity ranged from 77% for detection of CTCs in pre-cancerous lesions, to 87% for stage I-IV cancers. The researchers also calculated the accuracy of the results, which takes into account both sensitivity and specificity, and found that the accuracy of the test was high and ranged from 84 to 88% between pre-cancerous and cancerous samples. The accuracy of this test was superior to that of fecal occult blood testing (FOBT).

**Next Steps**

“Recent surveys have found that over 80% of patients who are reluctant to undergo colonoscopy screening would be receptive to a blood test over stool-based tests,” said co-author Ashish Nimgaonkar, MD, gastroenterologist and Medical Director in the Center for Bioengineering Innovation and Design at Johns Hopkins University, Baltimore, Maryland. “A number of studies have found that affordability was the number one reason for not being screened, however this test is highly affordable and can potentially cost less than $100.” Dr. Nimgaonkar also noted that
colonoscopy would still be the gold-standard diagnostic test and would be needed for tumor or polyp sample removal if an individual had a positive CTC test.

The authors are currently planning to validate the use of CTC testing in the general population in Taiwan and to conduct studies in the U.S. According to the authors, the technology used in this study potentially could be used with other solid tumors, such as breast, lung, and prostate cancer.

This study was sponsored by the Ministry of Health in Taiwan and Chang Gang Memorial Hospital.

View the full abstract.

For your readers:
- Guide to Colorectal Cancer
- Cancer Screening

More News From the Symposium

Nine additional abstracts exploring key issues in the treatment of gastrointestinal cancers will also be presented at the Gastrointestinal Cancers Symposium. These notable abstracts feature new insights for the treatment and management of gastric, esophageal, liver, and colorectal cancers.

Experts in gastrointestinal cancers are available on site to comment on the studies below.

Abstract 5:  
RAINFALL: A randomized, double-blind, placebo-controlled phase III study of cisplatin (Cis) plus capecitabine (Cape) or 5FU with or without ramucirumab (RAM) as first-line therapy in patients with metastatic gastric or gastroesophageal junction (G-GEJ) adenocarcinoma.

- Oral Abstract Session A
- Thursday, January 18, 2018: 3:00 – 3:09 p.m. PT
- The Moscone West Building, Level 2, Ballroom
- Charles S. Fuchs, MD
- Smilow Cancer Hospital, Yale New Haven Health
- New Haven, CT

Abstract 6:  
Robot-assisted minimally invasive thoraco-laparoscopic esophagectomy versus open transthoracic esophagectomy for resectable esophageal cancer: A randomized controlled trial.
Abstract 47:
The association of an exosomal form of PD-L1 with immunosuppressive activity and gastric cancer prognosis.

Abstract 206:
Randomized, open label, multicenter, phase II trial comparing transarterial chemoembolization (TACE) plus sorafenib with TACE alone in patients with hepatocellular carcinoma (HCC): TACTICS trial.

Abstract 209:
KEYNOTE-224: Pembrolizumab in patients with advanced hepatocellular carcinoma previously treated with sorafenib.
**Rapid-Fire Abstract Session**
Friday, January 19, 2018: 1:10 – 1:14 p.m. PT
The Moscone West Building, Level 3, Room 3014
Andrew X. Zhu, MD, PhD
Massachusetts General Hospital
Boston, MA

**Abstract 347:**
*Lanreotide for the prolonged control of carcinoid syndrome (CS) in somatostatin analog (SSA)-naïve or experienced patients.*

**Poster Session B**
Friday, January 19, 2018: 11:30 a.m. – 1:00 p.m. PT
Friday, January 19, 2018: 5:30 – 6:30 p.m. PT
The Moscone West Building, Level 1, West Hall
Edward M. Wolin, MD
University of Kentucky
Lexington, KY

**Abstract 553:**
*Nivolumab + ipilimumab combination in patients with DNA mismatch repair-deficient/microsatellite instability-high (dMMR/MSI-H) metastatic colorectal cancer (mCRC): First report of the full cohort from CheckMate-142.*

**Oral Abstract Session C**
Saturday, January 20, 2018: 11:00 – 11:09 a.m. PT
The Moscone West Building, Level 2, Ballroom
Thierry Andre, MD
Saint-Antoine Hospital
Paris, France

**Abstract 558:**
*SCOT: Tumor sidedness and the influence of chemotherapy duration on DFS.*
Abstract 724:

**Evaluation of outcomes over time (1998-2009) of patients (pts) with stage III colon cancer receiving adjuvant FOLFOX: Analysis of 7,230 patients from MOSAIC, C07, C08, N0147, AVANT, and PETACC8 trials in the ACCENT Database.**

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**About the American Gastroenterological Association Institute:**

The American Gastroenterological Association (AGA) is the trusted voice of the GI community. Founded in 1897, the AGA has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. The AGA, a 501(c6) organization, administers all membership and public policy activities, while the AGA Institute, a 501(c3) organization, runs the organization’s practice,
research and educational programs. On a monthly basis, the AGA Institute publishes three highly respected journals, *Gastroenterology* and *Clinical Gastroenterology and Hepatology*, and *Cellular and Molecular Gastroenterology and Hepatology*. The organization's annual meeting is Digestive Disease Week®, which is held each May and is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery. The AGA Research Foundation provides digestive disease research grants on behalf of the AGA Institute.

Learn more information about the American Gastroenterological Association, including how to join.

**About ASCO:**

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents more than 40,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube.

**About the American Society for Radiation Oncology:**
The American Society for Radiation Oncology (ASTRO) is the world’s largest radiation oncology society, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrist and other health care professionals who specialize in treating patients with radiation therapies. The Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three peer-reviewed journals, the International Journal of Radiation Oncology • Biology • Physics (redjournal.org), Practical Radiation Oncology (practicalradonc.org) and Advances in Radiation Oncology (advancesradonc.org); developed and maintains an extensive patient website, RT Answers (rtanswers.org); and created the Radiation Oncology Institute (roinstitute.org), a nonprofit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org, sign up to receive our news and follow us on our blog, Facebook and Twitter.

**About the Society of Surgical Oncology:**
The Society of Surgical Oncology (SSO) is the premier organization for surgeons and health care providers dedicated to advancing and promoting the science and treatment of cancer. The Society’s focus on all solid-tumor disease sites is reflected in its Annual Cancer Symposium, monthly scientific journal (Annals of Surgical Oncology), educational initiatives, and committee structure. The Society’s mission is to improve multidisciplinary patient care by advancing the science, education, and practice of cancer surgery worldwide. Learn more about the Society of Surgical Oncology.