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Contact: Shawn Farley
Public Relations Manager
ACRIN
703-648-8936
sfarley@acr.org

NCI Press Officers
301-496-6641
ncipressofficers@mail.nih.gov

Results of the National CT Colonography Trial: Questions and Answers

Key Points

- A large, multicenter trial of computerized tomographic colonography (CTC) indicates that virtual colonoscopy, or CTC, is highly accurate for the detection of intermediate and large colorectal polyps (Question 5)
- The study demonstrates the feasibility for CTC to be adopted into clinical practice as another colorectal cancer screening option (Question 8)

1. Why was this study needed?

Previous studies found that computerized tomographic colonography (CTC), also known as virtual colonoscopy, held promise as a screening method for colorectal cancer thanks to its accuracy, safety, cost-effectiveness, and patient acceptability. Given the fact that early detection of colorectal cancer has been shown to reduce mortality and that there are limitations to other colorectal screening approaches, there was a strong need to investigate whether CTC could be used as a screening tool.

Many consumer and public health organizations recommend that adults age 50 and older receive either colonoscopy every 10 years or some other form of colorectal screening, such as fecal occult blood testing or sigmoidoscopy. However, a large percentage (40-60 percent) of the over age 50 population in the United States remains inadequately screened. Additional screening options could translate into higher screening rates, earlier detection of cancer and polyps that potentially might develop into cancer, and ultimately fewer colorectal deaths.

Extensive preliminary CTC research has already been conducted and published. This study was designed to clinically validate CTC for detecting colorectal polyps 10 mm or larger in a multicenter trial. Although similar single-center trials are ongoing or recently published, validation of the technique at several centers by multiple radiologists is critical for establishing CTC's accuracy in comparison to colonoscopy. Researchers sought to generate data that would provide a balanced evaluation of the value and practicality of this screening tool.

2. What procedures were the study participants asked to follow?

Participants enrolled in the study were scheduled for a screening colonoscopy and agreed to also have a CTC exam on the same day as their colonoscopy (99 percent of enrollees underwent same day examination). The day before the exams, participants underwent one of three different colon-cleansing procedures depending upon the standard prescribed by their gastroenterology physician. This procedure was required for both the CTC and colonoscopy exams. The participants also were instructed to drink a solution that helps to distinguish any remaining stool from a polyp or cancer on the CTC images.

On the day of the exams, participants first had the CTC scan. During the exam, a small enema tip was placed in the rectum and carbon dioxide gas slowly inflated the colon until the patient felt full and the colon was adequately inflated. The inflated colon provides a better view of polyps or other abnormalities on the CT images. A set of CT images was produced with the participants lying on their back and stomach—holding their breath for a brief moment in each position. No sedation was required but a muscle relaxer called glucagon was administered to help prevent colorectal spasms, unless it was not advisable due to medical reasons or the participant refused it. The images were then sent to a computer for review by a radiologist.

Following the CTC exam, the colonoscopy was performed according to the standard procedures at each participating site. The colonoscopy was performed without the physician having any knowledge of the CTC results.

The CTC and colonoscopy reports were then compared after both procedures were completed. Participants were advised to have a repeat colonoscopy within 90 days if a polyp 10 mm or larger was detected on the CTC exam and not identified during conventional colonoscopy.

Two weeks after their exams, participants were sent a questionnaire about their screening experience.

3. Who was eligible to participate in the trial?

Both men and women age 50 years or older who were scheduled for screening colonoscopy and did not have symptoms of colorectal disease were eligible to participate in the trial. The researchers excluded individuals with serious medical conditions that would increase the risk associated with colonoscopy and people who had had colonoscopies within the past five years. Over 2,600 participants were enrolled in the study at 15 institutions across the U.S.

4. What was the primary scientific goal of the study?

Researchers sought to evaluate how well CTC identifies participants with at least one significantly large polyp (those 10 mm in diameter or more) using colonoscopy as the gold (or reference) standard.

5. What did the study find about CTC as a cancer screening tool?

This large, multicenter trial demonstrated that CTC is highly accurate for the detection of intermediate and large polyps. Using conventional colonoscopy as the gold standard, the study reported that CTC detected polyps 10 mm or larger in 90 percent of all participants who were confirmed to have a polyp of this size by colonoscopy.

6. Why are polyps the size of 10 mm or larger especially important to detect?

Generally, polyps of this size are more likely to develop into cancer. However, smaller polyps can also become cancerous, and this study demonstrated that CTC is able to detect polyps as small as 5 mm in width (about the diameter of a pencil) with high sensitivity. Sensitivity in this study was defined as the percent of patients with polyps detected by CTC that were later confirmed by biopsy as actually being polyps that have the potential to become cancerous. In particular the study estimated the following sensitivity values, depending on polyp size:

- 90 percent for polyps 9 mm in size or greater
- 87 percent for polyps 8mm in size or greater
- 84 percent for polyps 7mm in size or greater
- 78 percent for polyps 6mm in size or greater

7. How many people screened with CTC are expected to be referred for a subsequent colonoscopy?

The study results indicate that if all patients found to have a polyp 5 mm or larger by CTC were referred for a colonoscopy, less than 17 percent of patients would be required to undergo the additional exam. For those who will require a follow-up colonoscopy, the researchers recommend that referring physicians, endoscopists, and radiologists work together to provide same-day examinations to eliminate the need for a second colon cleansing.

8. What types of CT scanners were used in this study?

Study sites were required to use a 16-slice (or higher) CT scanner that can obtain 16 images per x-ray tube rotation. These types of CT scanners can acquire thinner slices for better image quality and can do a complete colorectal scan in a matter of minutes. Scanners used in this study include those manufactured by:

- General Electric (Milwaukee, Wis.)
- Siemens (Munich, Germany)
- Philips (Best, Noord-Brabant, Netherlands)
- Toshiba (Tochigi, Japan)

9. How much radiation is a person exposed to during a CTC exam?

The amount of radiation exposure during a single CTC exam is very small and is reported to be 50 percent less than a standard CT scan of the abdomen or pelvis.

As medical imaging exams have replaced more invasive and often more costly procedures, concerns have been raised that the cumulative radiation exposure from repeat exams could, over time, have adverse effects, particularly for at-risk populations.

Multiple factors should be taken into account when considering the radiation risk from CT scans -- the age of the patient, the number of scans the person has had in any given year and their lifetime, and the benefit to the patient. These factors will assist the health care provider in determining the risks and the benefits of a scan. If a scan is medically indicated, the benefit in practically all cases outweighs the small risk of potential harm. However, this risk should be considered in the decision-making process of both the patient and their physician.

10. Is it likely that these study results could be repeated?

Yes, it is likely that the study results can be widely reproduced in community settings if the study procedures are duplicated. A radiologist's competence to perform and interpret CTC exams is dependent upon adequate CTC training, which includes the review of example exams and familiarity with the appropriate software. The radiologists participating in this study were required to pass a certifying examination on the interpretation of CTC images. The study researchers suggest radiologic and other professional organizations work together to offer continuing education for radiologists to gain the competence to perform and accurately interpret CTC examinations. Also, establishment and certification of quality and competency standards would help ensure that the training is translated to the clinical environment.

11. Who conducted the study?

This study was conducted by the American College of Radiology Imaging Network (ACRIN), a cooperative cancer research group supported and funded by the National Cancer Institute (NCI). The trial principal investigator was C. Daniel Johnson, M.D., from the Mayo Clinic in Scottsdale, Ariz. Statistical and study methods were overseen by Mei-Hsiu Chen, Ph.D., a statistician within the ACRIN Biostatistics Center at Brown University's Center for Statistical Sciences in Providence, R.I.

The radiologists at each of the 15 participating sites served as the site principal investigator and had to have either interpreted 500 CTC exams or participated in a specialized CTC training session. In addition, all radiologists were required to pass a pre-study qualifying examination.

12. Where were the 15 study sites located?

- Beth Israel Deaconess Medical Center, Boston, Mass.
- Clinical Radiologists, S.C., Memorial Medical Center, Springfield, Ill.

- Johns Hopkins University, Baltimore, Md.
- Mallinckrodt Institute of Radiology, St. Louis, Mo.
- Mayo Clinic, Scottsdale, Ariz.
- Mayo Clinic, Rochester, Minn.
- MD Anderson Comprehensive Cancer Center, Houston, Texas
- Radiology Imaging Associates, Englewood, Colo.
- San Francisco Veterans Administration Medical Center, San Francisco, Calif.
- Scottsdale Medical Imaging, Ltd., Scottsdale, Ariz.
- UCLA School of Medicine, Los Angeles, Calif.
- UCSD Medical Center, San Diego, Calif.
- University of Chicago Hospital, Chicago, Ill.
- Virginia Commonwealth University Medical Center, Richmond, Va.
- Yale University, Connecticut Healthcare System, West Haven, Conn

13. Will researchers investigate other topics about CTC from the information collected as part this study?

Yes, when designing the trial, researchers identified several other important topics about CTC to be explored using the study data. These topics include:

- The effect of the differing colon preparations methods that were standard at each of the 15 participating sites.
- The willingness of individuals to undergo a repeat CTC as compared to a colonoscopy
- The ability of CTC to detect hard-to-find flat lesions in the colon
- Differences in the computer software the radiologists used to interpret the exams and their preferences
- The cost effectiveness of CTC relative to other colorectal screening tests
- What other parts of the body were examined during the CT scans and what was the potential to find other cancers outside the colorectum using this procedure.

The researchers are analyzing and documenting information on these topics, which will be reported at future scientific meetings and in medical journals.

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For further information about the ACRIN National CT Colonography Trial, please visit: <http://www.acrin.org/TabID/151/Default.aspx>.

For a press release on this trial, please go to <http://www.cancer.gov/newscenter/pressreleases/VirtualColonoscopyRelease>.

To arrange an interview with Dr. Johnson, please contact American College of Radiology (ACR) Public Relations manager, Shawn Farley, at 703-648-8936 or sfarley@acr.org.

For TV broadcast stations, video clips, b-roll and a VNR are available on PRNewswire (<http://www.prnewswire.com/broadcast/34638/press.html>), The NewsMarket (www.thenewsmarket.com), and via hardcopy by calling Shawn Farley at 703-648-8936.

For more information regarding colorectal cancer, please visit the National Cancer Institute at www.cancer.gov/cancertopics/types/colon-and-rectal.

ACRIN is a NCI Clinical Trials Cooperative Group. It is made up of investigators from over 100 academic and community-based medical facilities in the United States and several international institutions. ACRIN's mission is to develop information, through clinical trials of diagnostic imaging and image-guided therapeutic procedures that will result in: 1) the earlier diagnosis of cancer, 2) allaying the concerns of those who do not have cancer, and 3) improving the length and quality of lives of cancer patients. Further information about ACRIN can be found at www.acrin.org.

The American College of Radiology (ACR) is a national professional organization serving more than 32,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, with programs focusing on the practice of radiology and the delivery of comprehensive health care services.