

**COMPUTERIZED TOMOGRAPHIC COLONOGRAPHY: PERFORMANCE EVALUATION IN  
A MULTICENTER SETTING**

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**Status:**

Closed

**Statistician:**

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**Activation Date:**

July 20, 2000

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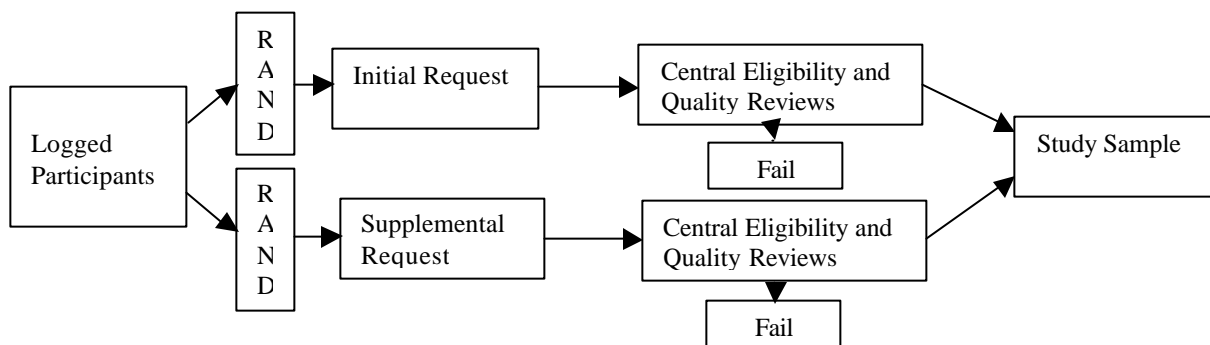
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**Schema**

**Objectives**

1. To evaluate the accuracy of CTC compared with pathology and colonoscopy for detecting clinically important colorectal neoplasia (*defined as lesions with diameter at least 1 cm*).
2. To examine physician image display preferences and interpretation time across three viewing platforms for CTC images.

**Participant Population**

This retrospective study used CTC images and colonoscopy results collected from participants examined at multiple institutions throughout the United States. Every effort was made to include participants of all ethnicities and genders. Criteria for inclusion/exclusion were:

**Inclusion criteria:**

1. CT acquisition parameters that meet the following minimal standards –  $\leq 5$  mm slice thickness,  $\leq 3$  mm reconstruction interval,  $\leq 2$  pitch, anatomic coverage of the entire colorectum, acquisition of both supine and prone data sets.

2. Complete colonoscopy performed by an experienced endoscopist within 30 days following the CTC examination.
3. Pathology reports for all endoscopically or surgically removed colorectal lesions, with the exception of polyps that are inadvertently dropped at the time of retrieval. In these cases, a photograph or videotape record of the lesion will suffice as proof of its existence. All studies will be accepted, including those with no lesions, with lesions of less than one cm, and with lesions of greater than or equal to 1 cm.
4. Studies may be transferred to ACRIN only after confirmation that informed consent was obtained from participants prior to the CTC examination.

Exclusion criteria:

1. CT acquisition parameters considered less stringent than above.
2. Incomplete colonoscopy, colonoscopy performed by an inexperienced examiner, or colonoscopy performed more than 30 days after CTC examination.
3. Absent pathology report in participants with endoscopically or surgically removed lesions.
4. Presence of colonic diseases other than polyps, cancer, or diverticulosis.
5. A suboptimal (*nondiagnostic*) CTC exam. Nondiagnostic studies would include a large amount of retained fluid (*at least 1 segment of the colon not visible on supine and prone views*), large amount of retained stool, > 2 colonic segments suboptimally distended, or severe breath hold artifacts.

**Summary of Study Design**

Participating institutions submitted logs of consecutive potentially eligible participants to the ACRIN Biostatistics Center (BC). The Protocol Statistician and Protocol Manager selected a random sample of participants for whom to request images. This sample was stratified to ensure an enriched population of participants with clinically important colorectal neoplasias. ACRIN notified each institution which participants were selected. CTC images were submitted to ACRIN, reviewed for quality by the PI, and reviewed for eligibility by the BC. The BC assigned each participant to one of three reading groups. CTC images for all of the participants in the study sample were loaded onto three workstations, each running different image display software, at the American College of Radiology's (ACR's) Philadelphia office.

Eighteen radiologists participated as readers in this study, each interpreting images on two different workstations (*one reading group on one workstation, and a second reading group on the other workstation*). A counterbalanced design was employed such that each participant's CTC images were to be interpreted by 4 radiologists on each of the three workstations, for a total of 12 interpretations.

**Per Case Reimbursement:** \$225.00

**Accrual Goals**

Images from 90 participants were to be accrued.

**Progress to Date**

The information in this Progress Report is based on data as of January 31, 2002. A total of 117 participants were enrolled into this study, 105 participant in July 2000 and 12 participants in October 2000. Six participants were declared ineligible, images from 17 participants did not pass central quality review, and images from 1 participant were not readable on all display platforms. The study sample thus included 93 participants.

Two radiologists with minimal experience interpreting CTC images received intensive on-site training, one at The University of Chicago and one at Mallinckrodt Institute of Radiology. All of the participating radiologists received brief training in a second software platform at the ACR. Readings occurred at the ACR from October 2000 through December 2000. Images for one participant were discarded on the first day of reading when they were not readable on all display platforms. This participant was replaced after the readers left, such that 2 readers interpreted images for only 29 of the 30 participants in reading group 2. Due to timing, 2 readers interpreted images for only 24 of the 33 participants in reading group 3, such that images for participants whose CTC examinations were obtained from the supplemental request were interpreted by 10 of the 12 readers.

There were no adverse events recorded for any participants.

**Registration by Institution**  
 Registration ended October 17, 2000

<u>Institution</u>	<u>Total Reg.</u>
Beth Israel Hosp	9
California, U of, Los Angeles	11
Chicago, The U of	14
Mallinckrodt Institute of Radiology	19
Massachusetts General Hosp	12
Mayo Clinic	35
New York U	8
San Francisco Veteran's Admin	9
Total (8 Institutions)	117

**Registration, Eligibility, and Quality Review**  
 Registration ended October 17, 2000; Data as of January 31, 2002

	<u>Number</u>
NUMBER REGISTERED	117
INELIGIBLE	6
Failed to re consent	1
Colonoscopy not performed	1
Colonoscopy before CTC	2
Images not sent	2
ELIGIBLE	111
INSUFFICIENT QUALITY	18
Unreadable on QC platform	6
Incomplete colorectum imaged	10
Excessive stool	1
Unreadable on display platform	1
SUFFICIENT QUALITY	93

**Participant Characteristics (Study Sample)**

Registration ended October 17, 2000; Data as of January 31, 2002

	<u>No Clin. Sig. Lesions (n=49)</u>		<u>≥ 1 Clin. Sig. Lesion (n=44)</u>	
<b>AGE</b>				
Median	63		64	
Minimum	34		40	
Maximum	82		83	
<b>SEX</b>				
Male	28	57%	24	55%
Female	21	43%	20	45%
<b>RACE</b>				
White	39	80%	39	89%
African-American	4	8%	0	0%
Hispanic/Latino	2	4%	0	0%
Asian	0	0%	1	2%
Unknown	4	8%	4	9%
<b>COLORECTAL SYMPTOMS</b>				
No	28	57%	27	61%
Yes	21	43%	16	36%
Unknown	0	0%	1	2%
<b>HIGH RISK FOR CR CANCER</b>				
No	12	24%	8	18%
Yes	34	69%	35	80%
Unknown/Missing	3	6%	1	2%

**Image Interpretations by Display Platform**

<u>Reader Number</u>	<u>General Electric</u>	<u>Vital Images</u>	<u>Mayo Clinic</u>	<u>Total</u>
1	30 (Group 1)	29 (Group 2)	0	59
2	0	33 (Group 3)	30 (Group 1)	63
3	33 (Group 3)	0	30 (Group 2)	63
4	30 (Group 2)	24 (Group 3)	0	54
5	0	30 (Group 1)	33 (Group 3)	63
6	30 (Group 1)	0	24 (Group 3)	54
7	0	30 (Group 1)	30 (Group 2)	60
8	30 (Group 2)	0	33 (Group 3)	63
9	0	33 (Group 3)	30 (Group 2)	63
10	30 (Group 1)	33 (Group 3)	0	63
11	30 (Group 1)	0	30 (Group 2)	60
12	30 (Group 2)	0	30 (Group 1)	60
13	33 (Group 3)	0	30 (Group 1)	63
14	33 (Group 3)	30 (Group 1)	0	63
15	29 (Group 2)	30 (Group 1)	0	59
16	0	30 (Group 2)	30 (Group 1)	60
17	33 (Group 3)	30 (Group 2)	0	63
18	0	30 (Group 2)	33 (Group 3)	63
<b>Total</b>	<b>371</b>	<b>362</b>	<b>363</b>	<b>1096</b>