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# Prevalence of polyps ≥6 mm on follow-up CT colonography in a cohort with no significant colon polyps at baseline

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ABSTRACT

*Aim:* Assess the prevalence of neoplasia ≥6 mm at repeat CT colonoscopy (CTC) in individuals with no significant lesions at baseline.

*Methods:* Individuals aged ≥18 years, with/without CRC risk factors, with no polyps ≥6 mm on baseline CTC (negative baseline) who underwent repeat CTC in a large HMO from 2001 to 2011 were retrospectively identified. Studies were reviewed by board-certified radiologists with experience interpreting CTC. Demographic details, CRC risk factors, and the number, size, and location of incident lesions were noted. Findings were classified using the C-RADS scale. Lesion prevalence at CTC-2 was determined, and study interval and risk characteristics of patients with- and without findings were compared.

*Results:* Our study included 636 individuals (369 men [58.0%]; mean age 59.9 years) with negative baseline CTC who underwent repeat CTC after a mean 4.6 year interval (SD 1.6 years). At baseline, 469/636 (73.7%) were at average risk for CRC; 418 remained at average risk for CTC-2 with 51 (8.0%) developing new risk factors in the interval between studies. At CTC-2, 47 participants (7.4%) presented 52 significant neoplasia: 35 polyps 6–9 mm, 14 polyps ≥10 mm, and 3 masses in 3/636 participants (0.47%). 2/3 masses, 6/14 polyps ≥10 mm (42.9%), and 12/25 polyps 6–9 mm (48.0%) were in individuals with risk factors for CRC. Histopathology was available for 12/52 lesions (23.1%): 8 tubular adenomas, 2 villous adenomas, 1 hamartomatous polyp, 1 case of normal tissue.

*Conclusion:* A mean 4.6 years after negative-baseline CTC, neoplasia ≥6 mm were seen in 7.4% of participants, including masses in 0.47%, supporting recommendations for a 5-year study interval.

## 1. Introduction

In 2012, there were 1.65 million new diagnoses and 835,000 deaths from colorectal cancer (CRC) worldwide [1]. CRC was the third most common cancer in men (920,000 cases) and second in women (733,000 cases) [1], with nearly 55% of cases diagnosed in developed countries [2]. A recent systematic review and meta-analysis [3] found "compelling and consistent evidence that screening can prevent most deaths from CRC." The study reported a reduction in CRC incidence and mortality of approximately 20–30% in intention to screen analysis and 30–45% in per protocol analysis from screening sigmoidoscopy, primarily in the distal colon. Screening colonoscopy was reported to offer an 80% reduction in CRC incidence and mortality in the distal colon and a 40–60% reduction in the proximal colon [4].

While colonoscopy remains the gold standard for detection of polyps as well as malignancies, with sensitivity of 88–98% for advanced neoplasia and 95–97% for CRC [5–8], CT colonography (CTC) has been shown to have sensitivity of 84–93% for advanced neoplasia and 96–100% for CRC [5,6,8–14]. The SIGGAR trial for patients with symptoms suggestive of CRC also reported no significant difference in detection rates of large polyps (≥10 mm) or CRC for CTC in comparison with colonoscopy [15].

The diagnostic yield from CRC screening depends not only on the accuracy of the examination performed and its interpretation, but also on the proportion of the population at risk that participates in screening and the interval between studies. CTC may be less burdensome for participants compared to colonoscopy due to the potential for reduced purgation regimens with good preservation of diagnostic capability

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[16,17], and may have potential to increase the rate of participation in routine screening examinations [5,18–21]. In addition, CTC's high sensitivity for detection of advanced neoplasia may be achieved with a lower rate of polypectomies and colonic perforations compared to screening colonoscopy [22]. CTC also enables evaluation of the entire colon as well as diagnosis of extra colonic findings. Based on current CTC performance, expert panels have concluded that it would be an effective screening test, or at least an alternative to colonoscopy for a significant proportion of individuals [4,8,12,21–32]. Most studies and guidelines have recommended repeat study once in 5–10 years when no polyp ≥6 mm is detected [4,25,29,30,32–38].

We aimed to assess the prevalence of findings at repeat CT colonography (CTC) examination in individuals without/with risk factors for colorectal cancer (CRC) who had no polyps ≥6 mm at the baseline study. We hypothesized that the prevalence of findings in both risk groups would increase over time.

## 2. Methods

The MOR Institute has established a national network of outpatient facilities that provide a wide range of diagnostic and interventional procedures for "Clalit Health Services." Clalit is the largest health maintenance organization (HMO) in Israel and one of the largest worldwide, with 3.7 million subscribers. We retrospectively reviewed imaging and clinical files for all CTC examinations performed at the Tel Aviv-area offices of the HMO from 2001 to 2011 to identify individuals who underwent repeat CTC examination. In the current study, we included individuals aged ≥18 years, with or without risk factors for CRC, who had no polyps ≥6 mm on the first examination (negative baseline study) and who underwent one or more repeat CTC examinations with an interval of at least 1 year between consecutive studies in order to exclude repeated studies due to technical failures or suboptimal purgation in the first study. Those who were evaluated for any reason other than detection of colonic neoplasia and those whose CTC examinations were incomplete or could not be interpreted were excluded.

Age and gender, relevant risk factors for CRC, indications for referral to CTC, the number of CTC examinations, interval between exams, and intracolonic findings at each study were recorded. The HMO is part of an open system. Follow-up optical colonoscopy and biopsy was obtained from HMO patient records when it was available. An Institutional Review Board approved the study and waived the requirement for informed consent.

### 2.1. CTC protocol and interpretation

Before CTC, individuals undergoing the study were placed on a 24-h clear liquid diet. When there was no contraindication due to chronic renal failure or congestive heart failure, two 5 ml doses of 0.9 g disodium hydrogen phosphate together with 2.4 g of anhydrous sodium dihydrogen phosphate (Soffodex, Deksol Pharma, Israel) until 2007 or sodium picosulfate/magnesium citrate (Pico-Salax) after 2007 were administered. In addition, two 10 mg bisacodyle tablets were taken morning and evening on the day prior to CTC. A preparation of 4 l of polyethylene glycol solution (Golytely, Braintree Laboratories, Braintree, MA, USA) was administered to individuals with chronic renal failure or congestive heart disease. Barium-based stool tagging was used (Baricat, E-Z-EM, Bracco Diagnostics, Lake Success, NY, USA).

Individuals were placed in the prone position and insufflation was performed by a physician. Following image acquisition in the prone position, individuals undergoing CTC examination were gently rotated to the supine position for a second acquisition. Data acquisition from the entire colon was performed in a single breath hold on a multislice 16–64 CT scanner (Philips Healthcare, Cleveland, OH, USA). Volumetric data were acquired from the full colon with 1.5–2.0 mm slice thickness, a 0.75–1.0 mm increment, a 0.5 s rotation time, 120 kVp, and 25–50 mAs for the prone study or 70–100 mAs for the supine study.

The studies were interpreted on dedicated workstations (V3D, Viatronix, Stony Brook, NY, USA or Philips Healthcare, Cleveland, OH, USA), independently, by one of two board certified, fellowship-trained radiologists (JB-Z., J.S.), both with experience in the evaluation of over 500 CTC examinations. The workstations were equipped with navigation software (Viatronix) for multiplanar reformations of the air-distended colon via a 3D endoluminal perspective through the colonic lumen in antegrade and retrograde directions. 2D images were used for the initial and primary interpretation and 3D images were used for confirmation. No computer-aided detection (CAD) software was used.

For the retrospective review, all individuals with positive findings at the second CTC (CTC-2) were identified and images acquired at the first CTC (CTC-1) examination for the same individual were compared to determine whether the lesion could be seen in retrospect (false negative). In cases of earlier false-negative findings, an attempt was made to determine why the lesion might have been missed. Findings at sequential examinations were localized by segment and then using specific local anatomy. Comparisons were performed by the same radiologists, working independently. Disagreements were resolved by consensus after thorough discussion between these two senior and colleagues, both highly experienced in interpreting CTC.

Polyps were classed as 6–9 mm, or ≥10 mm in maximum diameter; masses were defined as lesions with soft tissue attenuation and with maximal diameter > 3 cm [36]. Polyps ≤5 mm in diameter were identified and reported, but were not included as findings in the current study. Extracolonic findings were also recorded, but are not presented in the current study.

Individuals with positive findings at CTC, defined as a CT Colonography Reporting and Data System (C-RADS) C2, C3, C4 [36,39], were referred for follow-up by a gastroenterologist. The gastroenterologist determined whether colonoscopy was indicated, whether subsequent screening examinations would be performed with CTC or colonoscopy, and when the next examination should be performed.

## 3. Results

From 2001 to 2011, 22,247 individuals underwent at least one CTC study at the MOR Institute. Among them were 700 individuals (3.1%), including 403 men (58%) and 297 women (42%) who had at least one additional CTC study. Individuals with incomplete purgation and those with positive findings at CTC-1 were excluded, leaving 649 individuals who had no polyps ≥6 mm at CTC-1 (C-RADS 1) and who were considered to have negative baseline CTC examination. Thirteen additional participants were excluded because their CTC-2 studies were incomplete or could not be interpreted, leaving 636/700 (90.0%) individuals who met all criteria for inclusion in the current study (Fig. 1). There were 369 men (58.0%) and 267 women (42.0%) with mean age 59.9 years (range 27.9–92.9).

In 73.7% of subjects (469/636), the risk of developing colorectal cancer was average at the time CTC-1 was performed (Table 1). In comparison, at the repeat examination, only 418/636 (65.7%) individuals were at average risk due to increases in the percentage of examinations performed due to family history of colorectal cancer, abdominal complaints, personal history of inflammatory bowel disease, incomplete CTC, or positive fecal occult blood test.

At CTC-2, performed a mean 4.6 years (SD 1.6 years) after CTC-1, there were significant findings (C2–C4) in 47/636 individuals (7.4%), as shown in Tables 2 and 3. There were 35 polyps 6–9 mm, including 28 de novo lesions, six that had been visualized as polyps ≤5 mm on CTC-1 and grown in the interval between CTC1 and 2, and one seen retrospectively as a 7 mm polyp on CTC-1 (false negative). There were 14 polyps ≥10 mm, including nine de novo lesions and five that were seen retrospectively as polyps ≤5 mm after detection of the larger lesion on CTC-2. Three masses were found in 3/636 individuals (0.47%) (Figs. 2,

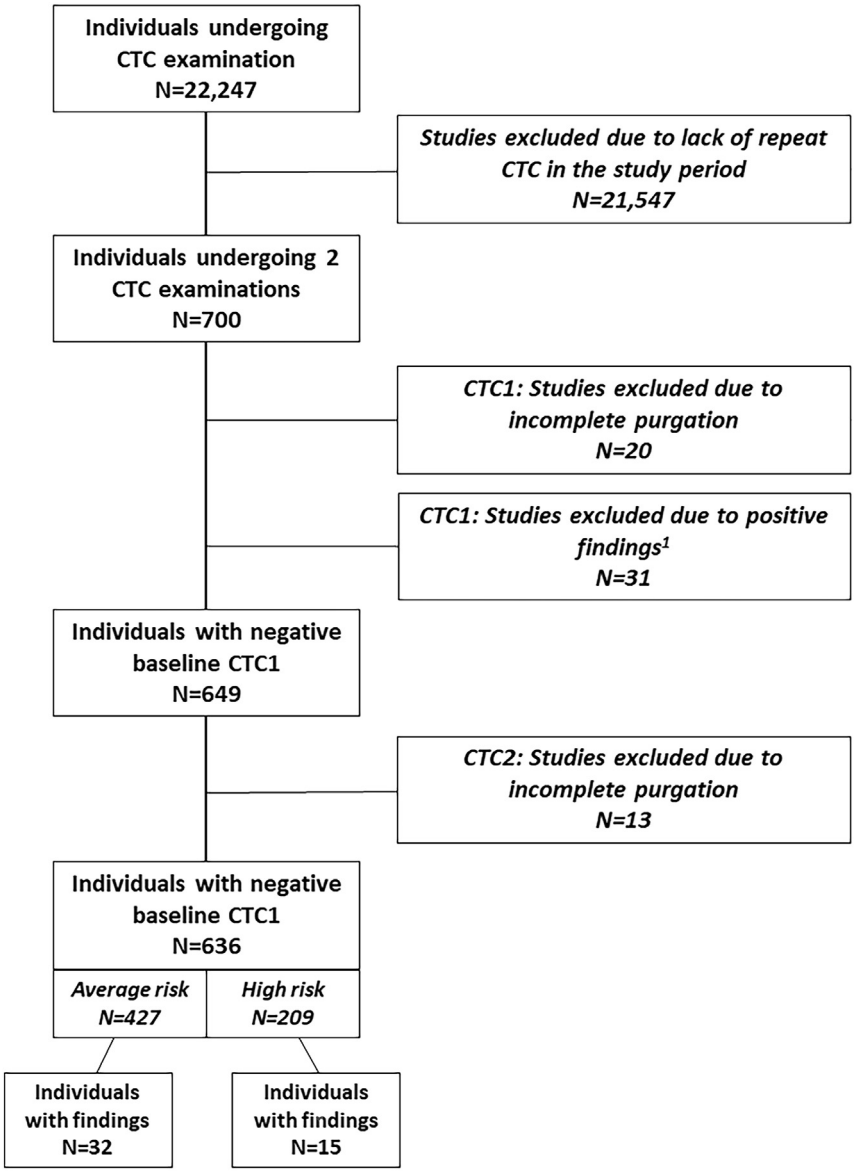


**Fig. 1.** Individuals undergoing two CT Colonography examinations.

**Table 1**
Reasons for referral at first and second CTC study in 636 individuals with negative baseline CTC examination.

| | CTC-1 | CTC-2 |
|---|---|---|
| Screening | 469 (73.7%) | 418 (65.7%) |
| Family history | 80 (12.6%) | 85 (13.3%) |
| Incomplete colonoscopy, review of a colonoscopy | 44 (6.9%) | 50 (7.8%) |
| Positive FOBT, anemia, weight loss | 21 (3.2%) | 34 (5.4%) |
| Abdominal complaints | 20 (3.1%) | 45 (7.1%) |
| IBD/diverticulitis | 1 (0.2%) | 3 (0.5%) |
| S/P malignancy outside of the GI tract, gynecological complaints | 1 (0.2%) | 1 (0.2%) |

CTC, CT colonoscopy; FOBT, fetal occult blood test; IBD, intestinal bowel disease; S/P, status post; GI, gastrointestinal.

3). Two masses, located in the sigmoid colon and the rectum, were seen retrospectively as 6–9 mm polyps on CTC-1, (false negatives, Figs. 2, 3), and the area around one mass in the rectum had been poorly visualized due to fluid accumulation. Lesions were seen in the cecum (5/52, 9.6%), ascending colon (5/52, 9.6%), transverse colon (11/52, 21.2%), descending colon (6/52, 11.5%), sigmoid (19/52, 36.5%), and rectum (6/52, 11.5%).

Histopathology was available for 12/52 lesions (23.1%) in 10/47 patients (21.3%) with findings at CTC-2. There were eight tubular adenomas, two villous adenomas, one hamartomatous polyp, and one case of normal tissue. An additional tubular adenoma, not detected on CTC-2 (false negative) was biopsied at colonoscopy and determined to be tubular adenoma.

## 4. Discussion

In this retrospective review, at CTC-2, performed after a mean 4.6 years between examinations, there were 52 neoplasia ≥6 mm in 47/636 individuals (7.4%), including three masses in three patients (0.47%).

The newly published systematic review and meta-analysis by Obaro et al. [37], which included 12 studies published from 2010 to 2017 presenting data for 19,867 patients, found 28 post-imaging cases of CRC diagnosed a mean 34 months after the first CTC study. The authors calculated a 4.42% post-imaging cancer rate in this large population, which is at the lower end of the 2.9–8.6% range reported for colonoscopy [40]. They concluded that a 5-year interval between CTC studies

**Table 2**
Findings at CTC-2 in 636/700 participants (90%) with no polyps ≥6 mm at CTC-1 (C-RADS 1) [36,39].

| Level of risk | C-RADS | Patients | Findings |
|---|---|---|---|
| Average | C1[a] | 394 | NA |
| 426/636 (67.0%) participants | C2[b] | 23 | 23 |
| 32/52 (61.5%) findings | C3[c] | 8 | 8 |
| | C4[d] | 1 | 1 |
| High | C1[a] | 195 | NA |
| 210/636 (33.0%) participants | C2[b] | 8 | 12 |
| 20/52 (38.5%) findings | C3[c] | 5 | 6 |
| | C4[d] | 2 | 2 |
| Total | C1[a] | 589 | NA |
| | C2[b] | 31 | 35 |
| | C3[c] | 13 | 14 |
| | C4[d] | 3 | 3 |
| | All | 636 | 52 |

[a] C1: Normal colon or benign lesions. No polyps or 1–2 polyps < 6 mm; recommend routine screening with CT colonography or colonoscopy in 5 years.
[b] C2: Intermediate polyp or indeterminate finding. 1–2 polyps 6–9 mm; recommend CT colonography polyp surveillance or colonoscopy with polypectomy.
[c] C3: Polyp, possibly advanced adenoma. Polyps ≥10 mm; ≥3 polyps 6–9 mm; recommend colonoscopy with polypectomy.
[d] C4: Colorectal mass, likely malignant. Lesion compromises bowl lumen, shows extracolonic invasion; recommend surgical consultation.

**Table 3**
New findings and changes in previously detected lesions in 47 individuals at CTC-2.

| | 52 neoplasia ≥6 mm | 47 individuals[a] |
|---|---|---|
| 6–9 mm polyps | 35 (67.3%) | 33 (70.2%) |
| De novo polyps | 28[a] | 26[a] |
| Growth from ≤5 mm to 6–9 mm | 6 | 6 |
| False negative on CTC-1, seen retrospectively | 1 | 1 |
| ≥10 mm lesions | 14 (26.9%) | 13 (27.7%) |
| De novo polyps | 9 | 9 |
| Growth from ≤5 mm to ≥10 mm | 5[a] | 4[a] |
| Masses | 3 (5.8%) | 3 (6.4%) |
| False negative on CTC-1, 6–9 mm polyp seen retrospectively | 2 | 2 |
| Poor visualization of the area due to fluid accumulation on CTC-1 | 1 | 1 |

[a] There were multiple lesions on CTC-2 in 3 individuals: 1 individual had 2 de novo 6–9 mm polyps and 2 lesions ≥10 mm that had grown from ≤5 mm on CTC-1 (total of 4 lesions), 1 with a de novo 6–9 mm polyp and a lesion ≥10 mm that was ≤5 mm on CTC-1, and 1 with 2 de novo 6–9 mm polyps.

is safe. Overall, 17/28 interval cancers (61%) were "attributable to perceptual error and were visible in retrospect," emphasizing the importance of careful adherence to optimal imaging and analysis protocols and rigorous training in interpretation of CTC examinations [37].

In contrast, findings in our study represent a somewhat higher rate of detection compared with a 2012 report by Kim and Pickhardt et al. [41]. At either colonoscopy or repeat CTC performed 1–5 years after the initial study in a screening population of 1011 individuals at average risk for CRC, they reported one incident colorectal adenocarcinoma (0.1%) diagnosed 35 months after an initial negative CTC. In addition, there were 11 advanced adenomas (1.1%) with no high-grade dysplasia at interval colonoscopy or CTC, and six polyps of 6–9 mm (0.6%) on repeat CTC. The lower prevalence could be partly due to underlying differences in CRC prevalence in the two populations. More recently Pickhardt and Kim et al. [42] reported the results of repeat CTC performed at a mean interval of 5.7 years from the baseline study in 1429 asymptomatic adults. Mass or mass-like lesions were seen in 0.3% (including one malignant and three benign lesions), polyps ≥10 mm in

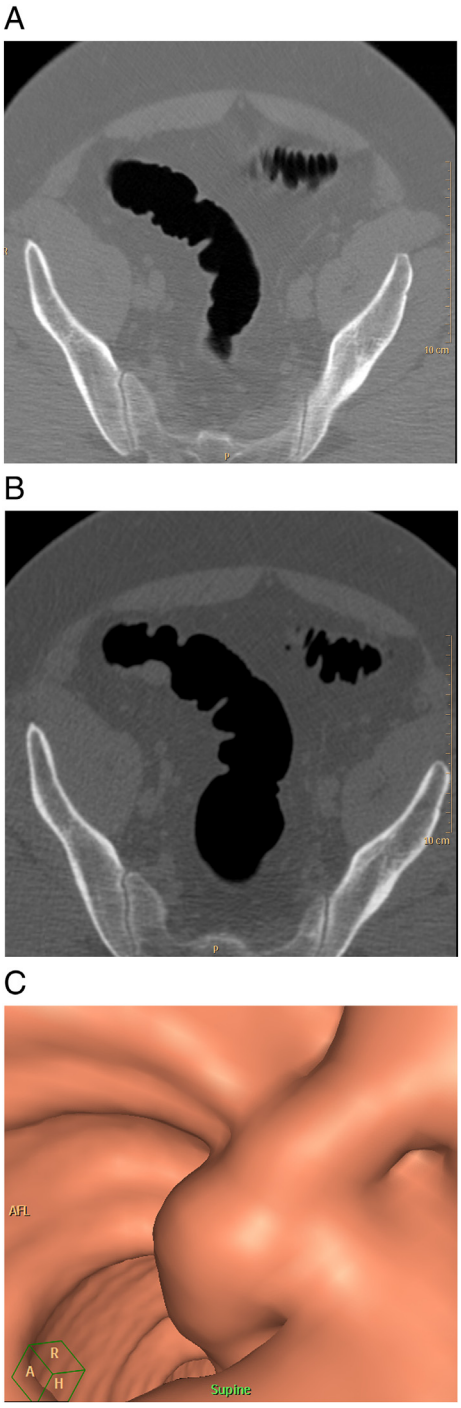


**Fig. 2.** A 52-year-old male underwent two CTC screening examinations. (A) No polyps were identified in the sigmoid colon in the initial study. (B) CTC-2, performed 4.5 years later, revealed a 1.6 cm pedunculated polyp in the 2D axial image, and (C) the 3D endoluminal view.

3.8%, and polyps 6–9 mm in 8.0%. Both reports concluded that a 5-year interval between routine screening CTC examinations represents safe CRC screening practice.

In 2005, an international group of radiologists active in the early development of CTC (Working Group on Virtual Colonoscopy) developed the C-RADS system for structured reporting on findings and recommended follow-up protocols [36]. The Group recommended surveillance with a 5–10-year interval between screening CTC examinations for individuals with no polyp ≥6 mm and no colonic abnormality that would increase the individual risk of developing CRC

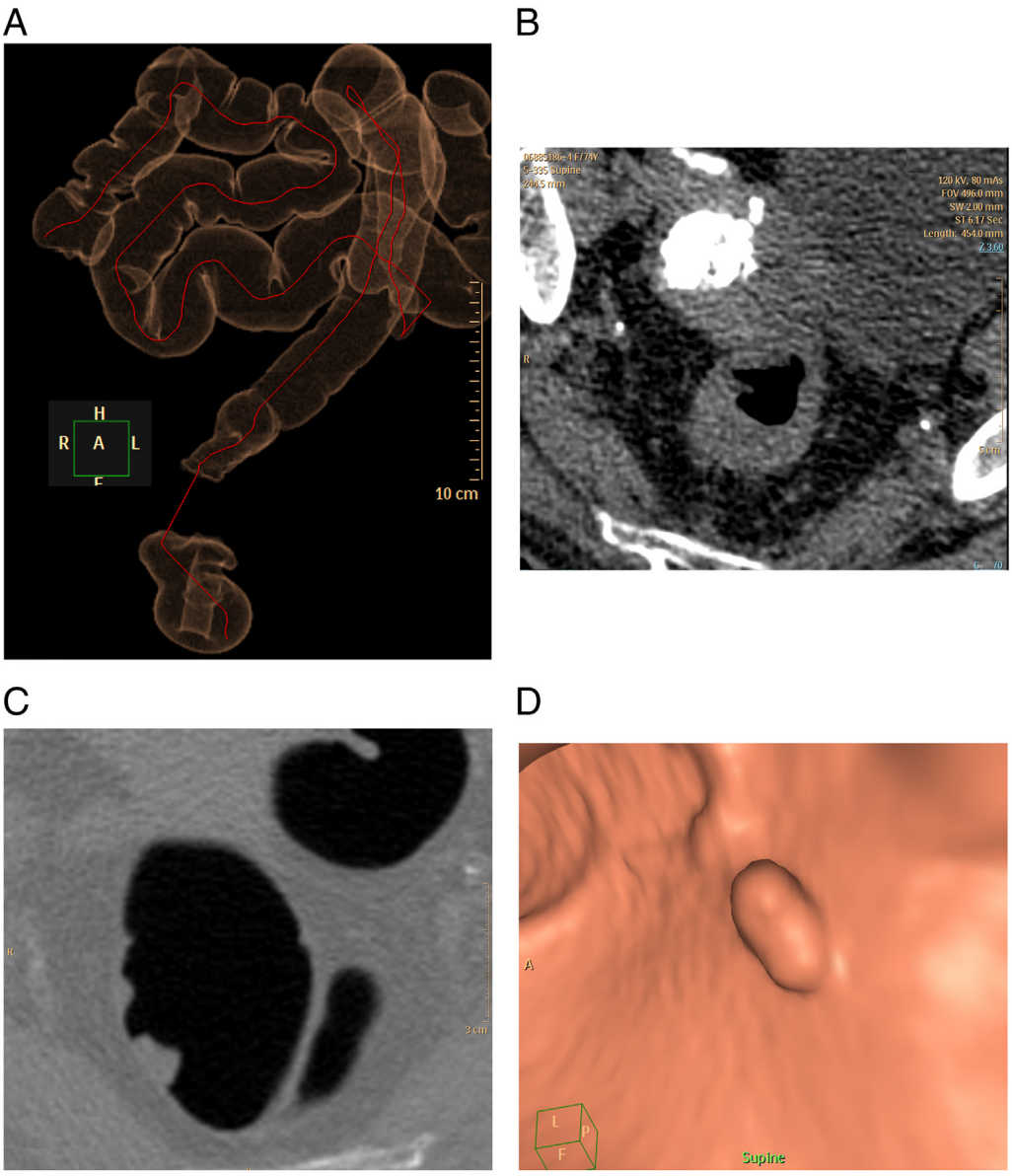


**Fig. 3.** A 69-year-old female underwent two CTC screening examinations. CTC-1 was read as negative; however, stool particles were noted in the rectum. Screening CTC-2 performed 5.5 years later demonstrated an apple core lesion in the rectum with marked narrowing of the lumen on the volume-rendered axial images (A) and volume rendered images (B). On retrospective evaluation of CTC-1 in volume rendered (C) and axial image (D), an 8 mm polyp in close proximity to untagged residual stool was seen, although the polyp had been missed when the study was initially reviewed (false negative).

(C-RADS 1).

Validation of CTC performance for the detection of large polyps and masses in multicenter trials and meta-analyses [5,6,8,12,13,15,37,43–45] has supported its inclusion in CRC screening guidelines. Current guidelines from professional societies and expert panels in the U.S. are reviewed by Medscape [46]. CTC is included as a first-line screening technique with recommendations for repeat screening once in 5 years by the American Cancer Society (ACS), the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology (ACR). The US Preventative Services Task Force (USPSTF) include CTC as a direct visualization screening test and recommend repeat CTC after 5 years. The American College of Gastroenterology (ACG) continues to recommend colonoscopy as the preferred screening examination but includes CTC as an alternative cancer detection test to replace barium enema, and to be repeated after a 5-year interval. In the U.K., CTC is recommended as an alternative for whole colon visualization following positive gFOBT, or in symptomatic individuals where colonoscopy is incomplete or contraindicated/unsuitable [25]. The European Society for Gastrointestinal Endoscopy (ESGE) and the European Society of Gastrointestinal and Abdominal Radiology (ESGAR) [30], and the EU Public Health Program of the European Commission [47] do not recommend CTC as a primary test for population screening or in individuals with a positive first-degree family history of CRC, but say that CTC is the radiological examination of choice and may be proposed for screening on an individual basis.

Taken together, findings from this wide range of studies suggest that CTC is an important technique for the early diagnosis of CRC that will likely play an increasing role in screening and surveillance, and that a 5-year interval for repeat CTC is reasonable in individuals with no polyps ≥6 mm at baseline as shown in the current study. Our study supports this 5-year interval in a general population setting.

The study has limitations. It is based on a retrospective review of digital medical records and imaging files and participants did not routinely undergo optical colonoscopy as a gold standard comparison study, precluding assessment of sensitivity or specificity. The lack of histology findings for most study participants with findings at CTC-2 in

our "open-system HMO" limits our ability to determine what proportion of polyps was adenomatous. However, our objective was not to compare the sensitivity and specificity of CTC with optical examination, but rather to use findings at repeat CTC as the basis for comparison. In the group for whom histopatholgy was available, most polyps were adenomatous. The fact that CTC studies were performed and interpreted in an independent freestanding imaging center more strongly supports general recommendations regarding the interval between screening and surveillance CTC examinations, since the center may be considered representative of other facilities in a population-based setting.

In conclusion, at repeat CT colonography performed a mean 4.6 years after baseline CTC, lesions ≥6 mm were seen in 7% of individuals with/without risk factors for CRC who had no significant colorectal lesions on the baseline study. These findings support current recommendations for a 5-year interval between CTC studies in individuals with no lesions ≥6 mm at baseline.

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