Abdominal Radiology (2019) 44:2971–2977
https://doi.org/10.1007/s00261-019-02099-9

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The yield and patient factors associated with CT colonography C-RADS results in a non-screening patient population

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Published online: 13 June 2019

Abstract

Objectives To determine the proportion of diagnostic computed tomography colonography (CTC) Reporting and Data System (C-RADS) categories in a non-screening population, and which patient factors are associated with a positive CTC (C2–4), a non-diagnostic CTC (C0), and potentially relevant extracolonic findings (ECF, E3–4).

Methods Diagnostic CTCs performed at a single academic center from 2017 to 2018 were retrospectively reviewed. For each examination, the indications, age, sex, admission status, and C-RADS categories were recorded. Multivariate logistic regression was performed of patient demographic factors and clinical indications, with adjusted odds ratios (OR) and 95% confidence intervals.

Results 1373 CTCs were included. The mean age was 66.4 ± 13 years (range 24–97). There were 782 women and 75 inpatients. The number of CTCs reported as C0–C4 were 194/1373 (14.1%), 970/1373 (70.6%), 77/1373 (5.6%), 86/1373 (6.3%), and 46/1373 (3.4%), respectively, and 134/1373 (9.8%), 960/1373 (69.9%), 173/1373 (12.6%), and 106/1373 (7.7%) CTCs were reported as E1–4, respectively. Factors that demonstrated the strongest associations were as follows: with C2–4, age groups 50–79 (OR 2.8, 95% confidence interval 1.4–6.1), 80–89 (6.2, 2.9–14.5) and ≥ 90 (7.6, 2.0–29.1), and inpatients (3.4, 1.8–6.4); with C0, age groups 50–79 (5.9, 2.2–24.4), 80–89 (9.8, 3.4–41.8), and ≥ 90 (22.5, 5.8–113.0), incomplete colonoscopy (3.2, 2.0–5.1) and melena or gastrointestinal bleeding (4.1, 1.8–9.4); and with E3–4, age groups 50–79 (1.6, 1.0–2.9), 80–89 (2.0, 1.1–3.9), and ≥ 90 (3.2, 1.2–8.8), and inpatients (2.3, 1.3–3.9).

Conclusion Older age is increasingly associated with a positive test, a non-diagnostic test and potentially relevant ECF. Inpatients are also associated with positive tests and E3–4 findings. Symptoms are not strongly associated with a positive CTC.

Keywords C-RADS, computed tomography colonography (CTC) · Colorectal cancer · Symptoms · Age · Multivariate regression

Introduction

Computed tomography colonography (CTC) is an accurate and cost-effective screening test for detecting colorectal polyps and neoplasms in asymptomatic patients [1, 2]. CTC is equivalent to optical colonoscopy (OC) for the detection of polyps sized ≥ 6 mm, but is safer, more cost effective, and more preferred by patients than OC [3]. Although less evaluated in the literature, CTC can also be used as diagnostic examination. As outlined in the 2014 American College of Radiology (ACR) and Society of Abdominal Radiology (SAR) Practice Parameter, diagnostic CTC can be used to assess symptomatic patients, or to further evaluate patients with a previous but less definitive screening test [4].

In our region, population screening for colorectal cancer (CRCa) is performed in average-risk adults ≥ 50 years of

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age with the fecal immunochemical test (FIT), and patients who test positive undergo OC. Our CTC program is used in a diagnostic fashion to evaluate patients with a variety of symptoms and/or abnormal bloodwork that raise the possibility of an advanced polyp or CRCa. This includes patients with positive FIT and incomplete OC, and symptomatic or anemic inpatients considered too high-risk for OC. Several patients undergoing CTC at our institution are outside the typical age range of average-risk screening.

Although several studies have shown that CTC is highly sensitive in detecting significant polyps and CRCa in symptomatic patients [5–8], the yield of diagnostic CTC according to the CT Colonography Reporting and Data System (C-RADS) guidelines [9] is less clear. Recent large-scale studies provide benchmarks for C-RADS categories of asymptomatic patients undergoing screening CTC [10–13]. However, the yield of CTC C-RADS categories is less established in patients that are symptomatic or outside the typical age range of routine screening [14–19]. It is also unclear what patient factors, such as admission status, symptomatology or incomplete colonoscopy, are associated with different C-RADS category results.

The goal of this study was to assess the proportion of C-RADS categories in our patient population undergoing diagnostic CTC as defined by the ACR-SAR Practice Parameter [9]. We also sought to determine what patient factors, if any, are associated with a positive test (C-RADS C2–4), a non-diagnostic test (C-RADS C0), and a test with potentially relevant extracolonic findings (ECF, C-RADS E3–4). Our hypotheses were that a higher proportion of CTCs performed in the elderly would be non-diagnostic, more often positive, and more often associated with potentially relevant ECF.

Methods

This HIPAA-compliant retrospective study was performed with approval from our institutional Research Ethics Board, who waived the need for patient consent. The study was conducted at the Queen Elizabeth II Health Sciences Centre, a tertiary care academic center in Halifax, Nova Scotia, Canada. The radiology information system was searched for all CTC examinations performed between 1 Jan 2017–31 Dec 2018. Of 1466 CTCs, we excluded 76 asymptomatic patients with history of polyps and 17 high-risk patients (3 with Lynch syndrome, 13 with inflammatory bowel disease, and 1 with Peutz-Jegher's), most of whom underwent CTC because of incomplete optical colonoscopy. The study therefore included 1373 diagnostic CTCs in patients with symptoms, new-onset anemia, or positive FIT. The mean and standard deviation in patient ages was 66.4 ± 13 years (range 24–97). There were 782 women and 591 men, 1298 outpatients and 75 inpatients.

For each examination, the following information was recorded: age; sex; outpatient or inpatient; and indication(s) for the study including any symptoms, anemia, or pertinent history. C-RADS scores were obtained from the interpreting radiologist's report, and if C0 was assigned the reason(s) why were recorded. In general, radiologists at our institution report C-RADS categories according to Ref. [9]; that is, C0 applies if a polyp ≥ 10 mm cannot be excluded, or a colonic segment is collapsed on both views. As in Ref. [13], C0 is not used to await a prior comparison, and the E0 category is not used. Whenever possible, our practice incorporates the ACR white papers on incidental findings at abdominal CT [20] to guide the need for imaging work-up of ECF at CTC. Instances where the requisition or report was unclear were reviewed by a board-certified fellowship-trained abdominal radiologist (initials blinded for review). For 136 patients with incomplete OC, as well as 75 inpatients, additional history was obtained from the electronic health record by (radiologist initials blinded for review).

CTC protocol

Our CTC bowel preparation regimen requires patients to start a liquid diet two full days prior to the study, and a bowel cleansing regimen with sodium picosulfate and magnesium citrate (Pico-Salax) in the morning and evening of the day prior to the examination. Barium sulfate (Readi-Cat, Bracco Diagnostics, Monroe Township NJ) was ingested in the morning and noon one day before the study, and 60 mL Gastrografin mixed with 8 oz of water was ingested in the late evening. Patients with incomplete OC but adequate bowel cleansing underwent same-day CTC; following patient recovery from OC, 30 mL of non-dilute barium and diatrizoate meglumine (Gastrografin, Bracco Diagnostics) was administered with two glasses of water, and the patient was scanned 2 h thereafter.

CTC examinations were performed on a Siemens Definition AS + 128-multidetector row CT (Siemens Healthcare, Erlangen, Germany). A rectal tube was inserted and an automatic carbon dioxide insufflator was used with the patient in the left decubitus position. Acquisitions were performed in supine and prone positions; if a patient was unable to lie prone, or if a segment of colon was noted to be underdistended by the technologist, a third acquisition in the decubitus position was performed [21]. CTCs were acquired in a single breath-hold at end expiration, using a fixed kVp of 120 keV, automatic tube current modulation (reference of 55 mAs), iterative reconstruction (SAFIRE, set to 3), pitch of 0.9, and 1 mm isotropic acquisition. Data were sent to TeraRecon (Aquarius INTuition Client 4.4.13.P2, TeraRecon Inc, Foster City, CA), where 1 mm triplanar reformations and three-dimensional volume-rendered images were generated. CTCs were interpreted using a combined two- and

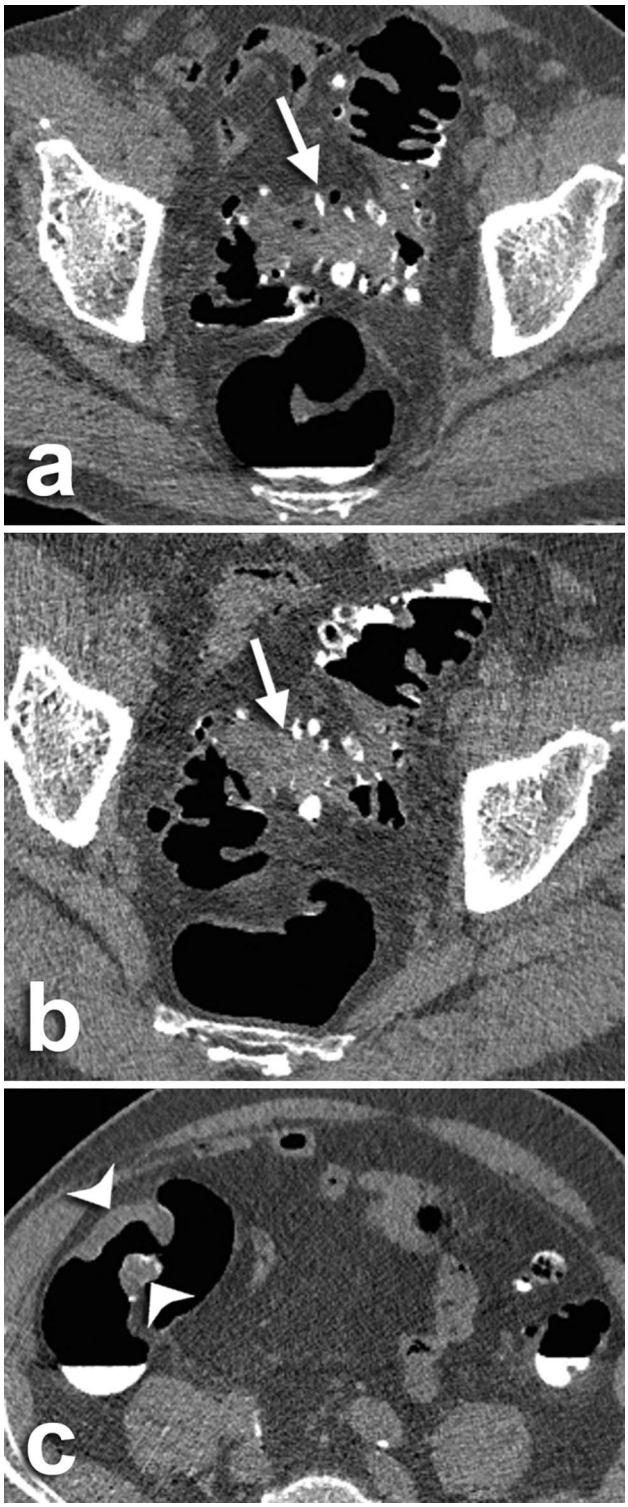

Fig. 1 A 90-year-old male undergoing CT colonography (CTC) for evaluation of iron deficiency anemia causing weakness and angina, with incomplete optical colonoscopy due to diverticulosis. Axial CTC images were acquired following routine colonic cleansing, fecal tagging and insufflation with carbon dioxide in the **a** supine and **b** prone positions. There is a segment of sigmoid colon that is underdistended on both views (arrows), resulting in a non-diagnostic (C0) examination. **c** On the same examination, there was an annular mass in the cecum causing luminal narrowing (arrowheads), highly suspicious for carcinoma. The patient underwent right hemicolectomy without biopsy, and on pathology this lesion was a grade 2, pT2N0 adenocarcinoma with clear margins and 0/18 negative lymph nodes

three-dimensional approach by one of seven board-certified, fellowship-trained abdominal radiologists (with 4, 5, 6, 8, 12, 13, and 14 years of experience).

Statistical analysis

The number of examinations assigned each C-RADS category was tabulated and histograms were made according to reporting radiologist. In order to evaluate the effect of age and facilitate comparison with the literature [10–13], C-RADS categories were also tabulated according to the following age ranges (in years): <50, 50–79, 80–89, and ≥ 90. Clinical indications including symptoms were tabulated according to frequency; for indications provided on at least 20 examinations, as well as the patient demographic factors (age group, sex, inpatient status), multivariate logistic regression was performed to assess which factors were associated with the following CTC results: a positive test (C-RADS 1 vs. 2–4); a non-diagnostic test (C-RADS 0); and potentially relevant extracolonic findings (E-RADS 3–4 vs. 1–2). Adjusted odds ratios (ORs) and 95% confidence intervals (CI) were obtained. Statistical analysis was performed with R (R Foundation for Statistical Computing, Vienna, Austria).

Results

The number of CTCs categorized as C-RADS 0–4 were 194/1373 (14.1%), 970/1373 (70.6%), 77/1373 (5.6%), 86/1373 (6.3%), and 46/1373 (3.4%), respectively. The most common reason for a C0 study was incomplete distention, found in 144/194 (74.2%); of these, 54 were related to diverticular-related strictures as shown in Fig. 1, or probable muscular hypertrophy from diverticulosis, 3 were from large ventral hernias, and 1 was secondary to carcinomatosis. Other C0 studies were assigned due to poor bowel cleansing (35/194, 18.0%), inability to tolerate the examination (9/194, 4.6%) of which 3 were due to large body habitus and claustrophobia, and imaging artifacts (6/194, 3.1%). Shown in Fig. 2 are histograms of assigned C-RADS categories according to reporting radiologist; there is some variability in C0–C1 and E1–2 categorizations; however, assignment of C2–C4 and E3–4 categories are relatively similar.

Shown in Table 1 is a breakdown of assigned C-RADS categories according to age group. The proportion of non-diagnostic (C0) CTCs was far fewer in younger age groups, ranging from 3/136 (2.2%) in patients <50 years old to 10/24

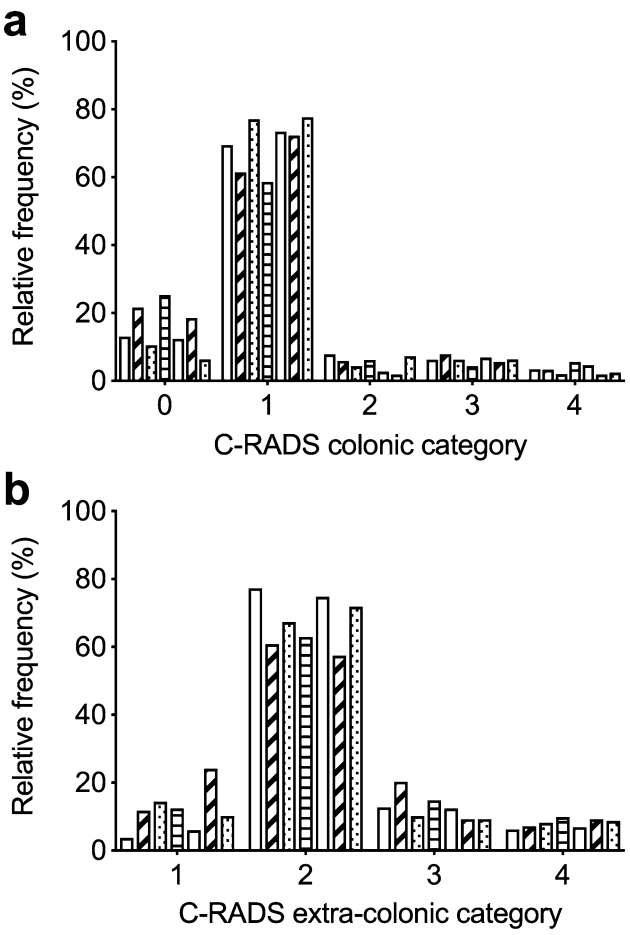

Fig. 2 Histograms of assigned CT Colonography Reporting and Data System (C-RADS) categories for **a** colonic and **b** extracolonic findings by seven abdominal radiologists

(41.7%) in patients ≥ 90. The percentage of positive CTCs (C2–4) also increased sequentially with age: 9/136 (6.6%) in patients < 50, 146/1017 (14.4%) in patients 50–79, 48/196 (24.5%) in patients 80–89, and 6/24 (25.0%) in patients ≥ 90. Similarly, the number of normal (C1) examinations decreased sequentially with age category, from 124/136 (91.2%) in patients < 50 years old to 8/24 (33.3%) in patients ≥ 90.

The number of CTCs categorized as C-RADS E1–4 were 134/1373 (9.8%), 960/1373 (69.9%), 173/1373 (12.6%), and 106/1373 (7.7%), respectively. Table 1 shows that the percentage of examinations without extracolonic abnormalities (E1) decreased with age, from 42/136 (30.9%) in patients < 50 to 0/24 (0%) in patients ≥ 90. For every age group, the majority (> 50%) of examinations were categorized with clinically unimportant ECF (E2). The proportion of examinations with potentially relevant ECF (E3–4) increased sequentially with age, from 17/136 (12.5%) in patients < 50, 201/1017 (19.8%) in patients 50–79, 51/196 (26.0%) in patients 80–89, and 10/24 (41.7%) in patients ≥ 90.

Shown in Table 2 is a list of patient demographic factors and clinical indications listed in order of frequency, and the adjusted odds ratios and 95% confidence intervals for the three CTC results evaluated. The most common indications were change in bowel habits, 283/1373 (20.6%); blood per rectum 255/1373 (18.6%); positive family history, 231/1373 (16.8%); pain, 203/1373 (14.8%); and anemia, 193/1373 (14.1%). Patient factors associated with a positive (C2–4) CTC were age groups 50–79 (OR 2.8, 95% CI 1.4–6.1), 80–89 (6.2, 2.9–14.5), and ≥ 90 (7.6, 2.0–29.1); males (1.5, 1.1–2.0); inpatient status (3.4, 1.8–6.4); and blood per rectum (1.7, 1.1–2.6). A non-diagnostic (C0) CTC was associated with the following: age groups 50–79 (5.9, 2.2–24.4), 80–89 (9.8, 3.4–41.8), and ≥ 90 (22.5, 5.8–113.0);

Table 1 Number and percentage of colorectal and extracolonic C-RADS categories for different age groups

C-RADS classification	All patients (24–97 years old) $n = 1373$	< 50 $n = 136$	50–79 $n = 1017$	80–89 $n = 196$	≥ 90 $n = 24$
Colorectal					
C0	194 (14.1)	3 (2.2)	135 (13.3)	46 (23.5)	10 (41.7)
C1	970 (70.6)	124 (91.2)	736 (72.4)	102 (52.0)	8 (33.3)
C2	77 (5.6)	4 (2.9)	56 (5.5)	16 (8.2)	1 (4.2)
C3	86 (6.3)	5 (3.7)	63 (6.2)	16 (8.2)	2 (8.3)
C4	46 (3.4)	0 (0)	27 (2.7)	16 (8.2)	3 (12.5)
C2–C4	209 (15.2)	9 (6.6)	146 (14.4)	48 (24.5)	6 (25.0)
Extracolonic					
E1	134 (9.8)	42 (30.9)	86 (8.5)	6 (3.1)	0 (0)
E2	960 (69.9)	77 (56.6)	730 (71.8)	139 (70.9)	14 (58.3)
E3	173 (12.6)	15 (11.0)	130 (12.8)	22 (11.2)	6 (25.0)
E4	106 (7.7)	2 (1.5)	71 (7.0)	29 (14.8)	4 (25.0)
E3–E4	279 (20.3)	17 (12.5)	201 (19.8)	51 (26.0)	10 (16.7)

C-RADS CT colonography reporting and data system

Table 2 Proportion of patients with each clinical indication or symptom, with adjusted odds ratios (OR) and 95% confidence intervals (CI) for the three CTC results evaluated

	n (percentage)	C2–C4 versus C1	C0 versus C1–4	E3–4 versus E1–2
Patient demographics				
Age 50–79 versus < 50	1017 (74.1)	**2.8 (1.4–6.1)**	**5.9 (2.2–24.4)**	**1.6 (1.0–2.9)**
Age 80–89 versus < 50	196 (14.3)	**6.2 (2.9–14.5)**	**9.8 (3.4–41.8)**	**2.0 (1.1–3.9)**
Age ≥ 90 versus < 50	24 (1.7)	**7.6 (2.0–29.1)**	**22.5 (5.8–113.0)**	**3.2 (1.2–8.8)**
Male sex	591 (43.0)	**1.5 (1.1–2.0)**	1.1 (0.8–1.6)	**1.4 (1.1–1.9)**
Inpatient status	75 (5.5)	**3.4 (1.8–6.4)**	1.7 (0.9–3.0)	**2.3 (1.3–3.9)**
Indication/symptom				
Change in bowel habits	283 (20.6)	0.9 (0.6–1.5)	1.3 (0.8–2.0)	0.8 (0.6–1.2)
Blood per rectum	255 (18.6)	**1.7 (1.1–2.6)**	1.4 (0.9–2.3)	1.2 (0.8–1.7)
Family history	231 (16.8)	1.1 (0.7–1.8)	1.2 (0.7–2.0)	0.8 (0.5–1.2)
Pain	203 (14.8)	0.8 (0.5–1.4)	1.4 (0.8–2.3)	1.3 (0.9–1.9)
Anemia	193 (14.1)	1.0 (0.6–1.7)	**1.6 (1.0–2.7)**	1.1 (0.7–1.7)
Constipation	144 (10.5)	1.3 (0.7–2.1)	**1.7 (1.0–2.9)**	0.9 (0.6–1.5)
Incomplete colonoscopy	136 (9.9)	1.1 (0.6–1.9)	**3.2 (2.0–5.1)**	0.9 (0.6–1.5)
Iron deficiency anemia	131 (9.5)	1.6 (0.8–2.8)	**2.2 (1.2–3.9)**	1.3 (0.7–2.1)
Diarrhea	104 (7.6)	1.4 (0.8–2.5)	1.0 (0.5–2.0)	1.3 (0.8–2.2)
Weight loss	82 (6.0)	1.1 (0.6–2.2)	**2.4 (1.4–4.1)**	1.3 (0.8–2.2)
Positive FIT	77 (5.6)	1.7 (0.9–3.3)	1.0 (0.4–2.1)	1.6 (0.8–2.8)
History of polyp(s)	71 (5.2)	1.0 (0.5–2.0)	1.5 (0.7–2.8)	1.3 (0.7–2.3)
Stool caliber change	69 (5.0)	1.0 (0.4–2.1)	1.2 (0.5–2.5)	1.0 (0.5–1.8)
Bloating	50 (3.6)	0.8 (0.3–2.0)	0.8 (0.3–2.0)	0.8 (0.3–1.7)
Melena or GI bleeding	32 (2.3)	0.5 (0.1–1.8)	**4.1 (1.8–9.4)**	1.9 (0.8–4.2)
History of cancer	32 (2.3)	1.0 (0.3–2.6)	1.0 (0.3–2.5)	1.9 (0.8–4.2)
Work-up of imaging finding	27 (2.0)	2.3 (0.7–6.2)	1.7 (0.5–5.1)	0.8 (0.2–2.2)
Diverticulitis	26 (1.9)	0.3 (0.0–1.4)	2.3 (0.8–6.2)	1.1 (0.4–3.0)

The ORs with CIs which do not cross 1 are highlighted in bold

CTC computed tomography colonography, *FIT* fecal immunochemical test, *GI* gastrointestinal

incomplete colonoscopy (3.2, 2.0–5.1); iron deficiency anemia (2.2, 1.2–3.9), anemia (1.6, 1.0–2.7), constipation (1.7, 1.0–2.9), weight loss (2.4, 1.4–4.1); and melena or gastrointestinal bleeding (4.1, 1.8–9.4). Only patient demographic factors were associated with potentially relevant ECF (E3–4): age groups 50–79 (1.6, 1.0–2.9), 80–89 (2.0, 1.1–3.9), and ≥ 90 (3.2, 1.2–8.8); males (1.4, 1.1–1.9); and inpatient status (2.3, 1.3–3.9).

Discussion

The results of our study provide percentages of C-RADS categories in a non-screening population that underwent evaluation with CTC. Although diagnostic CTC is highly sensitive for detecting CRCa and significant polyps [5–8], few studies have evaluated the proportion of C-RADS categories in such patients. Our yield of positive CTC was only marginally higher than other studies that evaluated symptomatic patients: 15.2% versus 13.6% in the study by Hock et al. [15], and 13.6% in the study by Netz et al. [17]. Interestingly, these positivity rates are comparable to the 14.4% benchmark established by Pooler et al. in an asymptomatic adult population aged 50–79 undergoing screening CTC [13]. These findings are consistent with the fact that bowel symptoms are generally common and not specific to CRCa or polyps [22–24]. One meta-analysis found that only rectal bleeding and weight loss were associated with CRCa, and not polyps [22]. Similarly in our study, the only symptom associated with a positive CTC was blood per rectum, whereas other associated factors were age, inpatient status, and male sex. Because the majority of patients with non-specific bowel symptoms do not have positive findings at OC or CTC, some authors argue that CTC—as the safer, less invasive and more cost-effective examination—should be the preferred test to evaluate such patients [17].

The potential drawbacks of CTC in such patients are the risk of a non-diagnostic CTC and the added burden of evaluating potentially relevant ECF. With respect to non-diagnostic CTCs, our study found a substantially higher proportion (14.1%) than other studies evaluating symptomatic patients: 44/1177 (3.7%) in [14] and 21/6108 (0.3%) in [15]. Of note, Ref. [15] found a high false-positive rate of 55/692 (7.9%), and perhaps the discrepancy in C0 rates reflects differences

in interpretation. The C0 rates of other studies are more difficult to discern; in the multicenter randomized SIGGAR trial, for example, inadequate examinations were only reported if no polyp was identified [7]; however, our practice is to assign C0 for examinations where a polyp ≥ 10 mm cannot be excluded, even if a polyp is identified elsewhere in the colon (ser Fig. 1 for example). Our study confirmed our hypothesis that C0 examinations are increasingly associated with older age, as well as patients with incomplete OC. To address our high C0 rate, we now have the reporting radiologist review all CTCs while patients are on the table, to assess adequacy and the need for a third acquisition in the decubitus position.

We also found a relatively high percentage of potentially relevant ECF in our study (E3–4, 20.3%). Although this is almost double than what Netz et al. found in their low-risk symptomatic population (333/3208 (10.4%) in [17]), their result is also less than that of the asymptomatic screening population evaluated by Pooler et al. (13.4% in [13]). Our proportion of E3–4 CTCs is lower than other studies evaluating symptomatic patients: 350/1177 (29.7%) in Ref. [14], and 296/1161 (25.5%) and 110/473 (23.3%) in Ref. [25]. Although ECF are often considered an undesirable consequence of screening CTC, this is not necessarily the case for diagnostic CTC in symptomatic patients, where ECF could potentially assist with managing a patient's abdominal pain or anemia, for example. In addition, our study showed that the proportion of CTCs with potentially relevant ECF increases substantially with advanced age. As emphasized in the ACR white papers on managing incidental imaging findings [20], the need to work up ECF must be balanced with a patient's life expectancy, comorbidities, and goals of care. In one study assessing ECF in a symptomatic population, only 55/350 (15.7%) of E3–4 findings were worked up after being taken into context by the clinical team [14].

A major finding of our study was the effect of age on the yield of CTC. Older age groups had increasingly higher percentages of C2–4, C0, and E3–4 examinations; for patients over 79 years old, for example, these percentages were 54/220 (24.5%), 56/220 (25.5%), and 61/220 (27.7%), respectively. A recent meta-analysis found a similar positivity rate of 23.6% in symptomatic patients ≥ 65 years old [18]. With half of all tests being positive or non-diagnostic, and the potential burden of evaluating ECF, one might argue against the use of CTC in older-aged patients. However, our endoscopists rely heavily on CTC as a safer alternative to OC in elderly, comorbid, and frail patients; our results show that CTC can avoid the need for OC in half of all patients. Moreover, OC in elderly patients is frequently difficult, with studies showing increased risk of incomplete procedure, inadequate bowel preparation, and adverse events [26–28]; for example, one study found that the risk for serious gastrointestinal adverse events was 75% higher in patients aged 80–84 versus patients aged 66–69 [27], and another study found that, of 76 patients aged ≥ 90, 24 (29.7%) had inadequate bowel preparation, 15 (19.7%) were incomplete, and 7 (9.2%) had adverse events [28].

Our study had limitations, including its retrospective nature and single-institution design. The referral patterns in our region are not necessarily representative of other centers, which may limit generalizability. Patient symptoms and history were elicited from the patient requisition when referred from their primary care physician, and from the requisition and electronic health record when admitted to hospital or after incomplete OC. We relied on the CTC reports for the C-RADS scores, and so results may be impacted by radiologist reporting trends. We did not evaluate outcomes following CTC; however, studies show that CTC is a highly accurate test with low inter-reader variability. One factor that was generally unavailable and so excluded from our study was patient weight or body mass index (BMI); it has been shown that the need for a third decubitus series increases with patient age and BMI, and this may represent an important patient factor as well [21]. We did not validate results from the multivariate regression analysis, and it is known that odds ratios typically decrease when trained models are applied to validation data. Despite these limitations, however, results from our study provide insight into the yield of CTC in a non-screening population of various ages.

In summary, our study evaluated the yield of diagnostic CTC in a non-screening population. The rate of positive CTCs was only slightly higher when compared to other CTC studies in symptomatic and asymptomatic patients, which indicates how common and non-specific bowel symptoms are; the only symptom associated with a positive CTC in our study was blood per rectum. Inpatients were associated with positive tests and potentially relevant ECF. The most important factor with respect to the yield of CTC was patient age: older age is increasingly associated with a positive test, a non-diagnostic test and potentially relevant ECF.

Compliance with ethical standards

Ethical approval IRB approval was obtained for this work.

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