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Potentially Important Extracolonic Findings at Screening CT Colonography: Incidence and Outcomes Data from a Clinical Screening Program

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Abstract

Objective—The impact of detection of extracolonic findings at screening CT colonography (CTC) remains controversial. Our objective is to analyze the incidence and outcomes of unsuspected potentially significant (C-RADS extracolonic category E4) findings in a clinical CTC screening population.

Methods—Over 98 months (April 2004 – June 2012), 7,952 consecutive asymptomatic adults (mean age 56.7 ± 7.3 years, 3,675 men, 4,277 women) underwent first-time screening CTC. Examinations were prospectively interpreted by radiologists within our abdominal imaging section and extracolonic findings recorded and categorized. Potentially significant (ie, C-RADS extracolonic category E4) findings were retrospectively reviewed with additional analysis of follow-up and ultimate clinical outcome.

Results—Overall, 2.5% (202/7952) of patients had a potentially significant (E4) extracolonic finding for which further imaging (55.9%, 113/202) or clinical follow-up (44.1%, 89/202) was recommended. No patients had multiple E4 findings. 22 patients were lost to follow-up. Of the remaining 180 patients, 68% (123/180) proved to have clinically significant disease, including 23% (42/180) with malignant or potentially malignant neoplasms and 32% (57/180) with abdominal aortic or other visceral artery aneurysms requiring treatment or surveillance. The most commonly involved organ systems included vascular (26.2%, 53/202), liver (14.9%, 30/202), genitourinary (13.9%, 28/202), gastrointestinal (9.9%, 20/202), lung (9.4%, 19/202), and gynecologic (6.9%, 14/202).

Conclusions—Potentially significant extracolonic findings in asymptomatic adults at screening CTC are uncommon, seen in 2–3% of cases. However, the majority of these findings will prove to be clinically significant, including a number of malignancies and aneurysms requiring treatment or surveillance.

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Introduction

CT Colonography (CTC) has been shown to be comparable to optical colonoscopy in the detection of colorectal cancer and advanced adenomas.[1, 2] CTC has also demonstrated high reliability,[3] cost-effectiveness,[4, 5] and patient acceptance.[6] Due to the cross-sectional nature of CTC, unsuspected extracolonic findings are inexorably detected in some patients, and the handling of extracolonic findings remains an active area of discussion in regards to widespread implementation of CTC for colorectal cancer screening.[7]

A system for categorization of extracolonic findings was established by the Working Group for Virtual Colonoscopy in 2005 as a component of the CT Colonography Reporting and Data System (C-RADS).[8] Prior research has demonstrated that a majority of extracolonic findings can be classified as clinically unimportant (C-RADS extracolonic category E2) at screening CTC despite low-dose technique and lack of intravenous contrast, and have estimated the overall rates of significant and potentially significant extracolonic findings at CT colonography.[9, 10] Several prior studies of extracolonic findings at CTC were performed using IV contrast[11] or included patients with colorectal symptoms,[12] limiting generalizability to CTC in the context of screening for colorectal cancer. Other studies performed without IV contrast have either generally considered potentially important and likely unimportant extracolonic findings (C-RADS extracolonic categories E4 and E3, respectively) together[13] or have instead focused on a particular subgroup of extracolonic findings (e.g. cancers)[14] without addressing extracolonic findings in a broader sense.

As detection of disease outside the colon is unavoidable, a more complete understanding of the frequency and nature of extracolonic findings is critical to placing into context the benefits and costs of screening CTC on the whole—especially if it is to be implemented on a larger scale—as well as in developing guidelines and recommendations for particular extracolonic findings. We present the first comprehensive analysis from a clinical screening practice of extracolonic findings with the greatest potential clinical importance. Our objective is to analyze the incidence and outcomes of unsuspected potentially significant (C-RADS extracolonic category E4) findings in a clinical CTC screening population.

Methods

This study was HIPAA-compliant and approved by our institutional review board. The requirement for signed informed consent was waived.

Patient Population

Between April 2004 and June 2012, 7,962 consecutive asymptomatic adult patients (mean age 56.7 ± 7.3 years, 3,675 men and 4,277 women) underwent first-time CT colonography for colorectal cancer screening at our single academic center. Exclusion criteria included a history of colorectal cancer, known inflammatory bowel disease, known polyposis syndromes, and a history of colorectal surgery. All examinations were prospectively interpreted by a board-certified radiologist practicing within our abdominal imaging section. In addition to colonic findings—which are beyond the scope of this manuscript—extracolonic findings were recorded and patients were prospectively assigned a C-RADS extracolonic

categorization based on the most significant finding (Table 1). For the purposes of this study, it is important to note that extracolonic findings were only deemed “potentially significant” if they were unknown at the time of screening CTC; previously described findings were excluded, and thus the E4 findings in this study were all unsuspected prior to screening CTC.

CTC Protocol and Technique

The CTC technique used in our screening program has been previously described.[15] In summary, patients underwent bowel preparation beginning one day prior to CTC using a cathartic osmotic cleansing agent. Prior to 2008, sodium phosphate was used for the majority of cases but discontinued in 2008 due to concerns of acute phosphate nephropathy; thereafter, magnesium citrate was used. Contrast material tagging of residual fluid and fecal material was achieved with 2.1% w/v barium and diatrizoate (Gastrografin). Colonic insufflation was achieved and maintained during the examination using automated continuous carbon dioxide delivered through a rectal catheter. Patients were routinely scanned in both supine and prone positions with decubitus positioning as needed. Images were acquired with 8-to-64-section multi-detector CT scanners using 1.25-mm collimation, 1-mm reconstruction interval, 120 kVp, and either a fixed tube current-time product of 50–75 mAs or tube-current modulation (range, 30–300 mA). No IV contrast was administered. To evaluate for extracolonic findings, supine CT acquisitions were routinely reviewed in the axial plane as 5 mm slices reconstructed at 3 mm intervals; thin (1.25 mm) slices, prone series, and reconstructions in other planes were used as needed on a case-by-case basis. Images were interpreted on a standalone work station (V3D Colon, Viatronix Inc, Stony Brook, NY) using three-dimensional reconstructions for primary polyp detection, as well as two-dimensional cross-sectional images for secondary polyp detection and confirmation.[16]

Follow-up and Data Analysis

Electronic medical record review was undertaken more than two years after the latest exams (November 2014) for all patients assigned a C-RADS extracolonic categorization of E4 in order to determine additional clinical and imaging follow-up, as well as to assess for any interventions and eventual outcome. Inpatient and outpatient provider notes, imaging studies, and pathology reports were included in the review. Patients who received primary care outside of our health care network were considered lost to follow-up, unless records were available for review. Data analysis was principally performed by the primary author (BDP). Student’s t-test and Fisher’s exact test were used to test for differences in continuous and categorical variables, respectively.

Results

Of 7,952 consecutive asymptomatic adults undergoing first-time colorectal cancer screening with CT colonography, 2.5% (202/7,952) had unsuspected extracolonic findings categorized as potentially significant (C-RADS extracolonic category E4). These patients averaged 60.5 ± 9.3 years of age, which is 3.8 years older than the overall cohort on average ($p < 0.0001$), and included 97 men and 105 women, which is not a significantly different ratio than the overall cohort ($p = 0.612$).

Extracolonic findings among these patients are summarized in Table 2. Commonly involved organ systems included vascular (26%, 53/202), liver (15%, 30/202), genitourinary (14%, 28/202), gastrointestinal (10%, 20/202), lung (9%, 19/202), gynecologic (7%, 14/202), pancreatic (2%, 5/202), adrenal (1%, 2/202), and breast (1%, 2/202). No patient had more than one C-RADS category E4 finding. Further evaluation of findings was recommended with additional imaging in 56% (113/202) and clinical follow-up recommended in the remainder. In total, 11% (22/202) deferred follow-up, were followed outside our medical system, or were lost to follow-up.

Of the remaining 180 patients, 68% (123/180) were found to have clinically significant pathology; these findings are summarized in Table 3. Significant findings included unsuspected frank or potential malignancies in 23% (42/180), including lymphoma (N=7), non-small cell lung cancer (N=5), renal cell carcinoma (N=4), invasive ductal carcinoma of the breast (N=2), transitional cell carcinoma (N=1), ovarian adenocarcinoma (N=1), adrenal cortical carcinoma (N=1), pheochromocytoma (N=1), islet cell tumor (N=1), adenocarcinoma of the appendix (N=1), peripheral nerve sheath tumor (N=1), and metastatic disease from various primary cancers (N=7).

Significant unsuspected vascular aneurysms were confirmed in 26% (46/180) of patients, including 22 abdominal aortic aneurysms (AAA's, >3 cm in diameter), 11 common iliac aneurysms (>1.5 cm in diameter), and 13 other visceral abdominal aneurysms. Of these, 20% (9/46, including 6 AAA's) had undergone surgical intervention (7 by endovascular aneurysm repair, 2 by open repair). Remaining vascular aneurysms were under surveillance at the time of record review.

Other previously undiagnosed clinically significant conditions were detected in 20% (35/180) of patients and included obstructive or staghorn urolithiasis (N=8), intestinal malrotation (N=7), polycystic kidney disease (N=5), cirrhosis of the liver (N=4), sarcoidosis (N=3), and endometriosis (N=2).

The remaining 32% (57/180) of patients had findings that ultimately proved to be frankly benign. Of these, 81% (46/57) were determined to be benign after additional imaging (N=42) or clinical follow-up (N=4) only. Only 6% (11/180) of E4 patients (11/7,952, 0.1% of the total screening population) underwent surgery or invasive biopsy to prove benign disease. Benign diagnoses at surgery included ovarian serous cystadenoma (N=2) or adenofibroma (N=1), pancreatic serous cystadenoma (N=1), pancreas tissue with lymphoepithelial cells, small bowel benign papillary choristoma (N=1), small bowel lymphectasia (N=1), mesenteric lipoma (N=1), appendiceal diverticulum (N=1), and hamartomas of the lung (N=1) and pelvis (N=1). Notably, all liver masses incidentally detected in this cohort in the absence of cirrhosis or other primary malignancy (N=18) were found to be benign cavernous hemangiomas at confirmatory imaging.

Discussion

Extracolonic findings remain among the most controversial topics with regard to widespread implementation of CT colonography for screening of colorectal cancer.[17] Specifically,

concerns have been raised regarding the frequency with which extracolonic findings lead to recommendations for further workup (which, in turn, lead to increased cost, patient anxiety, and possibly invasive procedures for what may ultimately prove to be benign disease), and how to practically deal with these cases. Often lost in the discussion is the magnitude and rate of beneficial diagnoses that arise which are otherwise unsuspected. The E4 category in C-RADS represents the extracolonic findings most likely to harbor these important diagnoses.

Prior studies have reported that more than 85% of asymptomatic adult patients undergoing screening CTC have either no extracolonic findings, or extracolonic findings that are clearly clinically unimportant (C-RADS extracolonic categories E1 and E2).[18] Of the remaining patients with findings that may be clinically relevant, a majority have extracolonic findings which are deemed likely insignificant (C-RADS extracolonic category E3), with only a small minority of patients demonstrating potentially significant extracolonic findings (C-RADS extracolonic category E4). Despite the concern for substantial numbers of required additional studies, the actual work up rate for all reported extracolonic findings has consistently been less than 10% in large CTC series.[13, 19–22]

Our study focuses on the E4 group, and shows that these potentially significant extracolonic findings occur in 2.5% of an average risk screening population. Given that the previously published overall work-up rate for extracolonic findings (E2–4) at our program is 6%[13], this means that 40% of the entire workup group consists of patients from the E4 category alone, which is notable considering the relatively small number of these patients. In our series, E4 patients were significantly older than the average for our entire cohort (60.5 vs 56.7 years, $p < 0.0001$), which is not surprising considering the positive correlation between age and many of the malignancies and other conditions we report. The gender distribution of our E4 patients was noted to be similar to the overall cohort. Additional imaging evaluation was recommended in just over half of E4 patients in this study, while the rest of the time the appearance of the finding at unenhanced CTC was enough to recommend specific clinical follow-up steps without the need for further imaging.

Importantly, nearly 70% of the patients with E4 findings in this study proved to have clinically significant disease after completion of workup. Vascular aneurysms (AAA's and others) were the single most commonly encountered category of disease, seen in 35 patients or 0.4% of the total cohort. By the conclusion of the record review period, nine of these patients had undergone endovascular or open aneurysms repair, potentially averting aneurysm rupture in what were otherwise asymptomatic individuals and demonstrating additional value of CTC. Downstream benefits of detecting this condition before symptomatic presentation are substantial. Modeling studies suggest that the beneficial diagnosis of this single incidental diagnosis alone balanced against the generated costs of work up of all incidental findings at CTC screening makes CTC cost effective compared to optical colonoscopy in addition to saving more lives.[19, 21]

Furthermore, 32 patients (0.4% of the total cohort) were ultimately diagnosed with previously unsuspected frank extracolonic malignancies—encompassing a myriad of organ systems—including several with metastatic disease. These cancers often consisted of slower-

growing entities such as lymphoma (N=7) and renal cell carcinoma (N=4), which may benefit from early identification and treatment. Although the true benefits and risk for earlier detection of these cancers is more difficult to determine, modeling studies suggest at least a mild to moderate overall benefit.[19] A number of additional diseases (or conditions predisposing to disease) were identified with proper treatment or surveillance initiated as appropriate in these cases.

Benign disease was ultimately diagnosed in just over 30% of E4 patients. These comprise the cohort in which screening CTC arguably has a negative effect; an incidental finding generates anxiety and cost but does not help the individual. It is important, then, to note that over 80% of these patients were ultimately diagnosed with benign findings with only additional imaging or clinical follow-up; a vast majority underwent additional imaging as recommended. A very small minority (N=11; 0.1% of the total cohort) ultimately underwent surgery to prove benign disease; a majority of these had either benign or indeterminate ovarian or pancreatic lesions on follow-up imaging, with surgery pursued for both diagnosis and definitive management. Some of these benign ovarian and pancreatic neoplasms presumably had malignant potential. Notably, all liver masses detected at screening CTC in the absence of primary cancer or cirrhosis were found to be benign liver cysts or cavernous hemangiomas on follow-up. Given the lack of clinically significant liver findings in this population, it is likely reasonable to consider isolated liver findings at screening CTC in patients without known primary cancer or signs of cirrhosis to be benign.

We acknowledge some limitations. Given the clinical nature of our practice, we are dependent upon primary care physician referral for our screening CTC patients, which may result in selection bias. Perhaps more importantly, we are also reliant upon primary care physicians for decisions regarding additional follow-up of patients, which may have led to inconsistent follow-up in some patients. Such limitations, however, are inevitable in any referral-based screening program, and we feel are mitigated by our large patient population. Finally, this study was conducted at a single large Midwest academic center; consequently, while our data are robust they may not necessarily generalize to other screening populations.

In conclusion, unsuspected potentially significant extracolonic findings (C-RADS category E4) at screening CTC are uncommon. However, when encountered they are high yield, representing a diverse spectrum of clinically significant pathology requiring treatment or continued surveillance. Detecting significant but clinically silent extracolonic disease may represent an additional benefit of screening CTC. Furthermore, surgery or invasive biopsy was avoided in the vast majority of patients with ultimately benign findings.

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Figure 1.
Flow diagram of study cohort

Figure 2. —Unsuspected Significant Extracolonic Findings at Screening CT Colonography

A: 57-year-old man. Abdominal aortic aneurysm seen at CTC (top) and follow-up CTA (bottom), later repaired by EVAR. **B:** 64-year-old woman. Lymphoma manifesting as lymphadenopathy at CTC (top) and follow-up contrast-enhanced CT (bottom). **C:** 70-year-old woman. Non-small cell lung cancer at the left lung base, seen at CTC (top) and follow-up chest CT (bottom). **D:** 63-year-old man. Renal cell carcinoma seen at CTC (top) and follow-up contrast-enhanced CT (bottom). **E:** 63-year-old man. Adrenal cortical carcinoma seen at screening CTC (top) and follow-up contrast-enhanced CT (bottom). **F:** 59-year-old woman. Metastatic disease in the liver seen at CTC (top) and follow-up contrast-enhanced CT (bottom), breast cancer primary. **G:** 50-year-old woman. Staghorn calculus of the left kidney, seen at CTC axial (top) and scout (bottom) images. **H:** 57-year-old man. Autosomal dominant polycystic kidney disease seen at CTC (top) and follow-up contrast-enhanced CT (bottom).

Table 1

C-RADS Extracolonic Finding Categories, adapted from Zalis, et al, 2005[8]

Category	Description
E0	<u>Limited Exam</u> . Compromised by artifact; evaluation of extracolonic soft tissues is severely limited.
E1	<u>Normal Exam or Anatomic Variant</u> . No extracolonic abnormalities visible.
E2	<u>Clinically Unimportant Finding</u> . No work-up indicated (e.g. simple liver or kidney cysts, cholelithiasis without cholecystitis, vertebral hemangioma).
E3	<u>Likely Unimportant Finding, Incompletely Characterized</u> . Subject to local practice and patient preference, work-up may be indicated (e.g. minimally complex kidney cyst)
E4	<u>Potentially Important Finding</u> . Communicate to referring physician as per accepted practice guidelines. (e.g. solid renal mass, lymphadenopathy, aortic aneurysm)

Table 2

Location of Extracolonic Findings

Extracolonic Finding	N
Abdominal Aortic/Common Iliac Aneurysm	35
Liver Mass	26
Kidney Mass	20
Lung Nodule/Mass	19
Visceral Abdominal and Other Aneurysm	18
Adnexal Mass	14
Other Gastrointestinal	12
Gastrointestinal Mass	8
Lymphadenopathy	8
Urolithiasis	8
Other Genitourinary	8
Pancreas Mass	5
Other Liver	4
Adrenal Mass	2
Breast Mass	2
Other	13
Total	202

Table 3

Significant Unsuspected Extracolonic Findings

Malignant Tumors		N
	Lymphoma	7
	Non-Small Cell Lung Cancer	5
	Renal Cell Carcinoma	4
	Transitional Cell Carcinoma	1
	Ovarian Adenocarcinoma	1
	Appendiceal Adenocarcinoma	1
	Islet Cell Tumor	1
	Pheochromocytoma	1
	Adrenal Cortical Carcinoma	1
	Nerve Sheath Tumor	1
	Breast Invasive Ductal Carcinoma	2
	Other Metastatic Cancer	7
Other Tumors		
	Mucinous Tumor	4
	Mature Teratoma	3
	Renal Oncocytoma	3
Vascular Aneurysms		
	Abdominal Aortic Aneurysm	22
	Common Iliac Aneurysm	11
	Visceral Abdominal/Other Aneurysm	13
Other		
	Obstructing/Staghorn Urolithiasis	8
	Intestinal Malrotation	7
	Polycystic Kidney Disease	5
	Cirrhosis	4
	Sarcoidosis	3
	Endometriosis	2
	Renal Agenesis or Dysgenesis	2
	Inflammatory Bowel Disease	1
	Early Acute Appendicitis	1
	Colovesical Fistula	1
	Hydrosalpinx	1
Total		123