

The Challenges of CT Colonography Reimbursement

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CT colonography has been shown to be an effective method to screen for colorectal cancer. However, at present, full endorsement and reimbursement for screening CT colonography, particularly by the US Preventive Services Task Force and CMS, respectively, are absent, so this screening option is infrequently used, and optical colonoscopy remains the de facto standard screening option. The authors summarize the past accomplishments that led to the current state of reimbursement and outline the remaining challenges and road to full acceptance and reimbursement of screening CT colonography nationally.

Key Words: CT colonography, colorectal cancer, technology adoption

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INTRODUCTION

After the endorsement of CT colonography (CTC) as an acceptable method to screen the colon for polyps and masses in 2008 by the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the ACR [1], most experts expected full endorsement by Medicare and by most insurance companies within a few years. Five years later, there are persistent challenges to full national acceptance and reimbursement for screening CTC. Nevertheless, many referring physicians remain unaware that many CTC examinations are reimbursed by large private payers such as United Healthcare and Cigna, depending on the examination indication and the specific insurance carriers' policies. Many nonscreening examinations done for diagnostic indications are reimbursed by Medicare if optical colonoscopy (OC) was incomplete. Herein, we summarize some of the past successes and the remaining challenges and our vision for the path to full CTC reimbursement.

HISTORICAL RATIONALE AND OBJECTIONS

After the publication of the US Department of Defense CTC screening trial [2], the ACRIN[®] National CT Colonography Trial [3], and other studies in the United

States and Europe, CTC was viewed as a test that had undergone sufficient validation regarding its sensitivity and specificity for the detection of neoplastic polyps > 10 mm [4]. The key advantages touted for CTC were its minimally invasive nature; no need for sedation, making it suitable for an outpatient setting; patients' ability to return to normal activities immediately after the examination; its safety, with a very low risk for perforation [5]; and lower cost relative to OC. Several important publications addressed prior concerns regarding guidelines for training readers [6] and structured reporting of the results of CTC [7]. Additional advantages of CTC compared with OC were published [8], including avoidance of unnecessary biopsies of small, non-neoplastic polyps; a better safety profile for CTC in patients in whom OC is medically contraindicated; and patient preference for CTC [9].

The advocates of OC raised concerns that included the need for patients with polyps to undergo OC for polyp biopsy or removal; the lower sensitivity of CTC for small polyps and flat lesions; the impact of extracolonic findings (ECFs), particularly on the overall cost-effectiveness of CTC; and the cumulative risk of radiation, particularly for patients undergoing follow-up examinations. The US Preventive Services Task Force (USPSTF) categorized CTC in 2008 as lacking sufficient evidence to fully assess its benefits and harms and assigned it an I rating (insufficient evidence) rating. Preferable ratings are A, meaning high certainty of net benefit of the test, and B, meaning high certainty that the net benefit of the test is moderate to substantial [10-12]. A and B ratings would be required for the USPSTF to advance CTC, and such a recommendation would be heavily relied upon by CMS when making its determinations. CMS evaluated the efficacy of CTC in

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May 2008 as part of a national coverage analysis. In a meeting of the Medicare Evidence Development and Coverage Advisory Committee in November 2008, only USPSTF was specifically invited to present its position. In May 2009, CMS found that evidence did not support reimbursement of CTC for Medicare beneficiaries [13,14] and concluded that there was “insufficient evidence on the test characteristics and performance of screening CTC in Medicare-aged individuals.” CMS expressed concern for ECFs, radiation, and overall cost-effectiveness as well. Yet the requirement for data specific to Medicare-age persons did not have precedent [15].

RESPONSES TO KEY CONCERNS

An ACR Colon Cancer Committee white paper [6] and subsequent publications responded to some of the concerns of CMS and USPSTF. CTC outcomes measures and cost-effectiveness were reanalyzed and confirmed to be favorable specifically for the Medicare-age population [16,17]. ACR subcommittees continue to update the CT Colonography Reporting and Data System (C-RADS) guidelines [7] and the appropriateness criteria for colorectal cancer screening [18]. The ACR practice guideline for the performance of CTC in adults is being updated for 2014 in conjunction with the Society of Abdominal Radiology and the Society of Computed Body Tomography and Magnetic Resonance [19].

Need for Polyp Removal

Using C-RADS guidelines [7], physician referral of a patient to OC for biopsy is estimated at 8% for screening patients, 12% for Medicare-age patients, and probably slightly higher for nonscreening patients. Current best practice is to offer the option for rapid interpretation of CTC with a same-day OC option [20], obviating the need for repeating the colon cathartic and scheduling an examination on a different day.

Cost-Effectiveness

Cost-effectiveness is officially not a metric considered by the USPSTF or CMS. Nevertheless, cost-effectiveness was reanalyzed for the ACRIN National CT Colonography Trial patient cohort, and microsimulation models were developed to assess outcomes and costs of CTC compared with other colorectal cancer screening tests in the average-risk Medicare population [17]. Knudsen et al [17] concluded that CTC could be a cost-effective option under one or both of two important conditions: (1) that the reimbursements for CTC remain substantially lower than for OC and (2) if CTC substantially improves compliance with colorectal cancer screening. Kim et al [16] also found CTC to be highly cost effective in Medicare-age patients. A recent *New York Times* series on the high cost of health care focused on OC as a significant source of excessive costs due to high fees, anesthesiologist costs, and frequent surveillance intervals [21].

ECFs

Reports on asymptomatic screening cohorts have demonstrated that the incidence of ECFs requiring treatment or further investigation ranges from 5% to 9% [22-25]. However, actual workup rates of ECFs differ and are lower than “recommended” workup rates, and medical complications related to the workup of ECFs are extremely rare. Patients ranging in age from 65 to 79 years (ie, the Medicare-age population) were found in one study to have a 15.4% (89 of 577) incidence of potentially important ECFs and a workup rate of 7.8% (45 of 577), in which the majority of important diagnoses were vascular aneurysms [16]. The ACRIN National CT Colonography Trial found that 16% of its patients had ECFs categorized as potentially requiring additional tests or treatment [16]. Recent work studying screening patients in a multicenter noncathartic CTC trial by Zalis et al [26] demonstrated that 16% of trial participants had indeterminate ECFs (C-RADS category E3) [7], while only 3% were categorized as potentially clinically significant (C-RADS category E4). Medical record review revealed that only 5.5% of participants subsequently underwent additional diagnostic workup because of ECFs reported on index CTC. Other recent large series showed that the workup rate for combined category E3 and E4 ECFs was 6.1% [27] to 8.8% [28]. A slighter higher workup rate of 9.6% was described in a large prospective Dutch trial [29], with several beneficial ECFs found (eg, abdominal aortic aneurysms, extracolonic malignancies). Similar results were found multiple recent trials as well as in an analysis of Medicare-age patients [30-32].

The incidence of “significant” ECFs increases in symptomatic patients, in those with known colorectal lesions, and if CTC is performed using intravenous contrast or with a higher radiation dose [22,24,33-37]. A report in a mixed screening and symptomatic population found that 4% of patients had significant ECFs, but half of those were previously known [38]. In a mixed population of 749 female patients, the incidence of gynecologic ECFs was found to be 9.5%, and additional workup was done in 20% of these [39]. A meta-analysis found that the incidence of resectable extracolonic neoplasms found on CTC was 0.9%, which is similar to the frequency of nonmetastatic colon cancers detected by OC in asymptomatic adults [40].

Detection of unsuspected malignancies on CTC at an early stage may lead to increased survival rates and favorable outcomes, as shown in a cohort of > 10,000 patients. This study reported an overall detection rate of unsuspected cancer of 1 per 200 (58 of 10,286) in asymptomatic adults [41], with more than half being stage I disease. Thus, the overall detection rate of extracolonic malignancy (1 per 300 cases) is greater than that of invasive colorectal cancer (1 per 500 cases).

Some studies have found that 0.2% to 2% of asymptomatic patients will undergo surgery for ECFs [2,22,23,27]. The mean cost of additional workup

incurred as a result of potentially significant ECFs (not including surgical expenses) has been estimated at \$24 to \$34 per patient [22,23,25,27,42], although individual patient costs may be higher.

Hassan et al [43] modeled the benefit and cost of detecting extracolonic neoplasms and abdominal aortic aneurysms on screening CTC. This strategy was compared with screening OC for adenomatous polyps and screening ultrasound for aortic aneurysm (which is reimbursed by Medicare). The CT colonographic model resulted in slightly more life-years gained but an incremental cost-effectiveness ratio that dominated the OC-ultrasound model. The additional cost savings of the CT colonographic approach were due mostly to the detection of aortic aneurysms (not cancers), and the OC-ultrasound model was more cost effective only when the sensitivity of CTC for large polyps dropped to < 61% [43].

Thus, the majority of ECFs found on CTC will not require or undergo further workup. The incidence of clinically significant (and previously unknown) findings warranting further evaluation ranges from 5% to 9% in the vast majority of published trials, and the incidence of surgical intervention in the subset of patients with significant findings is about 2%. As the ACR accumulates more data in the National Radiology Data Registry for CTC, process and outcome measures for large numbers of patient nationally will be illuminated.

Radiation

Experts in the Health Physics Society have opined that the conservative assumptions of the linear no-threshold model are an oversimplification and that no detrimental effects of medical radiation have been directly observed [44]. Several societies, including the American Association of Physicists in Medicine, discourage the calculation of risks for exposures below 50 mSv [44-46]. CTC is a low-radiation dose procedure and gives much lower doses than a routine CT scan. The paradigm established by the ACRIN National CT Colonography Trial published in 2008 [3,47] was to use an effective tube current-time product of 50 mAs and a tube voltage of 120 kVp.

Methods to further reduce CT radiation dose have become widely available and used in CTC. These include reductions of tube current and tube voltage, automatic tube modulation, and iterative reconstruction [48,49]. Reducing the tube voltage to 100 kVp resulted in a 20% decrease in volume CT dose index and a 16% decrease in dose-length product but only a minimal decrease in 3-D image quality for the range of patient body mass indexes studied [49]. Reducing tube current-time product to 25 mAs combined with a 40% adaptive statistical iterative reconstruction technique was found to decrease the radiation dose during CTC to 50% below currently accepted low-dose techniques without significantly affecting image quality [50]. Ginsburg et al [51] studied the use of tube current-time products of 15 and 30 mAs

in CTC and showed that the radiation dose for CTC can be reduced by 40% and 70% below commonly used doses for overweight and normal-weight patients, respectively, by using a body mass index-adjusted dose reduction approach. CTC doses can now be used that are at or below the natural background radiation in the United States (about 3 mSv/y) [27].

Even taking into account the prior relatively higher radiation doses used in CTC and assuming that the linear no-threshold model is correct, the benefit-to-risk ratio of CTC evaluated by comparing the potential lives saved by colorectal cancer screening with CTC and the potential deaths from induced cancers from medical radiation was large in favor of CT colonographic screening, ranging from 24:1 to 35:1 [52,53].

Legislative Activity

Support for the use of CTC for colorectal cancer screening has extended to the House of Representatives and the Senate. The first CTC legislation was submitted on May 28, 2010, during the 111th Congress. Representative Danny Davis of Illinois and cosponsors Representatives Mark Kirk and Dan Boren introduced the Virtual Screening for Colorectal Cancer Act of 2010 (House Resolution 5461) to the House of Representatives. This bill requested amendment of Title XVIII of the Social Security Act to provide Medicare coverage for screening CTC as a colorectal cancer screening test [54]. The bill was introduced to the House Committee on Energy and Commerce and the House Committee on Ways and Means and then referred on to the Subcommittee on Health. However, no action was ever taken on the bill.

CTC legislation was submitted again on March 8, 2012, in the 112th Congress (House Resolution 4165), by Representative Ralph Hall of Texas as well as Representative Danny Davis [55]. The CT Colonography Screening for Colorectal Cancer Act of 2012 proposed amendment of Title XVIII of the Social Security Act to cover screening CTC as a reimbursable colorectal cancer screening test under Medicare. The bill was referred to the House Committee on Energy and Commerce and the House Committee on Ways and Means. A companion bill, Senate Bill 2265, introduced on March 29, 2012, in the Senate by Senator James Inhofe of Oklahoma [56], was referred to the Senate Committee on Finance. Unfortunately, neither of the bills ever made it out of committee review, and they were never enacted.

There is continued interest and persistent support for CTC from congressional members, and on March 6, 2013, Representatives Ralph Hall and Danny Davis reintroduced the CT Colonography Screening for Colorectal Cancer Act of 2013, (House Resolution 991), in the 113th Congress [57]. This bill is cosponsored by Representative Tom Cole of Oklahoma and Representative Ander Crenshaw of Florida and has been

referred to the Subcommittee on Health of the House Committee on Energy and Commerce as well as the House Committee on Ways and Means. Support for this bill is increasing nationally, and key groups are calling on Congress to pass it, including the ACR and the Colon Cancer Alliance, the latter a patient advocacy group for colorectal cancer.

The Path to Full Reimbursement

Medicare does not currently have a national coverage policy for screening CTC. Additionally, although a service may be covered at the discretion of Medicare contractors on the basis of a local coverage determination, local carriers are prevented by CMS regulations from covering screening for patients without symptoms [58]. Thus local coverage determinations may help provide coverage for indications such as after failed diagnostic colonoscopy, after failed screening colonoscopy, for preoperative cancer staging, and in patients on anticoagulation therapy or with histories of unsuccessful or unsafe colonoscopy [59]. However, there is significant state-level variation and also differences on the basis of the particular local carrier.

Individual states have followed different pathways toward reimbursement for screening CTC. In 2009, the Delaware insurance commissioner issued a mandate that all health insurance policies in the state must include CTC as an approved procedure for colorectal cancer screening [60]. This mandate followed the endorsement of the Delaware Cancer Consortium and Delaware's secretary of health and social services. In January 2013, Connecticut state law was revised to mandate coverage of colorectal cancer screening in accordance with American Cancer Society guidelines, which include CTC every 5 years as an option. Under prior law, insurers had to follow recommendations established by the American College of Gastroenterology. National insurance carriers have also moved toward broad reimbursement for screening CTC, including Cigna, United Healthcare, and Unicare. Various Blue Cross Blue Shield carriers, depending upon the state, also provide reimbursement for screening CTC.

The key to CMS's agreeing to reimbursement is the upgrade of the USPSTF status of screening CTC to grade A or B; ongoing legislative efforts are also important. It is encouraging that USPSTF endorsed the use of annual CT scans for the detection of lung cancer in individuals considered to be at high risk for the disease [61]. On the basis of the literature to date and indications from CMS and USPSTF, we expect that in the future, an initial recommendation to endorse CTC for colorectal cancer screening will be made and opened for public comment. Although peer-reviewed data already published support and justify full reimbursement for screening CTC, our continued efforts should concentrate on the publication of data to support the scientific arguments for CTC and on public opinion and legislation.

TAKE-HOME POINTS

- Although many carriers reimburse for diagnostic or screening CTC, CMS has not yet agreed to reimburse for screening CTC.
- Key concerns raised in the past included the sensitivity of CTC for small polyps, examination performance in the Medicare-age population, the impact of ECFs, cost-effectiveness, and the cumulative risk of radiation.
- Scientific publications to date have satisfied the substantial concerns, and most experts acknowledge that reimbursement for screening CTC in the Medicare population is justified.
- A USPSTF upgrade of CTC to an A or B rating is required for CMS to modify its recommendation. Reconsideration of the CTC grade is expected in 2013, and we hope for an upgrade to at least a B rating.
- Continued scientific publications, legislative efforts, and education of the public as to the value of CTC should be our focus.

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