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 USPFTF 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