

PRACTICE MANAGEMENT

Trends in Gastroenterology Reimbursement and Practice Management

CT Colonography: Impact of Recent Findings on the Future Practice of Colorectal Cancer Screening

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Colorectal cancer (CRC) is the second most-diagnosed cancer in the United States. It affects men and women equally and is unique among cancerous and precancerous lesions in that if found early enough, it can be removed successfully to avoid progression. Nonetheless, CRC represents a significant public health problem in that a large proportion of people eligible and recommended for screening are not undergoing examination.

Optical colonoscopy currently represents the gold standard in procedures to detect CRC and precancerous colonic lesions and polyps, as it allows for diagnosis and removal in the same examination. The invasive nature of optical colonoscopy and the need for a cleansing preparation represent major hurdles to improving patient compliance to screening and successful early detection of CRC. Even the utilization of other modalities to screen patients as recommended by the US Preventive Services Task Force, namely barium enema, flexible sigmoidoscopy, and fecal occult blood testing, have not significantly affected patient compliance with CRC screening.

The emerging diagnostic modality of computed tomography (CT) colonography, in which the colon is inflated with air and imaged via noninvasive CT, has been under investigation as an alternative modality in the hope of improving rates of CRC screening compliance in the general population. Although a number of the early CT colonography studies were initiated in the radiology community, the advent of three-dimensional viewing software has led gastroenterologists to consider undergoing training in its interpretation.

The Era of CT Colonography?

Several recent studies have raised the profile of CT colonography as a viable alternative to optical colonoscopy and may change the way CRC screening is conducted in the future.

The recently completed National CT Colonography/American College of Radiology Imaging Network (ACRIN) 6664 Trial, funded by the National Institutes of Health, was conducted to compare the accuracy and sensitivity of CT colonography versus optical colonoscopy in detecting both advanced neoplasia and resectable polyps. The study enrolled 2,531 participant patients in 15 US centers and randomized them to undergo either CT colonography with subsequent referral for colonoscopic resection in the event of positive findings or initial examination and immediate resection via optical colonoscopy. Although the complete results of the trial have not yet been published, it was recently announced that the sensitivity of the CT colonography procedure was 90% for adenomatous colorectal lesions 1 cm or larger in diameter, which was on par with the sensitivity achieved with optical colonoscopy. Overall, 392 polyps 6–9 mm in size were detected in 258 patients, and 155 lesions 1 cm or larger were found in 132 patients. Among these polyps, 29% were detected in the right colon, 17% in the transverse colon, 38% in the left colon, and 16% in the rectum. Sensitivity was 84% or greater for polyps 7 mm or larger, and specificity measured 86–89% across all lesions. Two-dimensional CT readings required an average of 19 minutes, and three-dimensional CT read-

ings averaged 25.5 minutes. Overall, these preliminary results, released in September 2007, showed that CT colonography approaches the detection rate of optical colonoscopy in terms of intermediate lesions (5–10 mm) and large lesions (≥ 1 cm).

A second study, published in October 2007 in the *New England Journal of Medicine*, looked at CT colonography as utilized in 3,120 consecutive adult patients and compared it to primary optical colonoscopy screening in 3,163 patients at the University of Wisconsin Medical Center. The investigators found, as with the ACRIN study, that CT colonography and optical colonoscopy yielded similar detection rates for advanced neoplasia and concluded that CT colonography could be recommended as a primary screening test before therapeutic optical colonoscopy.

Persistent Questions

If these two studies establish CT colonography as a viable alternative to optical colonoscopy in terms of accuracy and level of polyp detection, what questions still need to be answered before it can be adopted in widespread clinical practice?

We must remember that with all noninvasive procedures for colonic screening, as well as with flexible sigmoidoscopy, if polyps are detected, they will require removal and histologic evaluation. Ultimately, CT colonography must be viewed as a strategy to improve rates of CRC screening. A screening test is defined as one performed on a patient in the absence of signs or symptoms. If a noninvasive method can be utilized without sacrificing accuracy of screening, polyp detection rates can be improved and, theoretically, incidence of colon cancer will decrease. The same can be said for other emerging technologies, such as colon capsule endoscopy and self-propelling colonoscopes. However, whether this scenario actually pans out in real-world utilization remains to be seen.

People (both patients and some physicians) perceive CT colonography as noninvasive. Although there is no insertion of an intravenous line and no infusion of dye, the colon must still be inflated with air, which requires placement of a tube in the rectum and an element of discomfort that may or may not prove a significant barrier to improving screening adherence. In addition, until “prep-less” stool tagging is perfected, patients must undergo a colon-cleansing preparation prior to performance of the examination.

Questions also remain regarding the protocol once a polyp is detected with CT colonography. The natural history of small polyps needs to be studied and better understood before CT colonography imaging can be deemed truly useful. Do we have clear-cut evidence to

determine, in the event of finding a diminutive polyp of 5 mm or less, whether it is safe to watch and wait? Should the patient be referred for optical colonoscopy and immediate removal once a lesion is detected. Polyps of less than 5 mm may be of concern down the road and the natural course of small polyps requires further study. If we do watch and wait, when should the patient come back for repeat screening? In 1 year? In 3 years? Should the patient have repeat screening with CT colonography or with optical colonoscopy?

These questions also inform our considerations regarding compensation for CT colonography. Can patients with polyps larger than 5 mm but smaller than 1 cm be followed, or does detection of such lesions warrant expeditious referral for optical colonoscopy? Assuming that 5 patients undergo optical colonoscopy, and 1 of the patients is found to have polyps, the cost to the system is the sum of 4 screening colonoscopies and 1 colonoscopy with polypectomy. If CT colonography is performed as the primary screening tool and if the cutoff for referral to optical colonoscopy is for lesions greater than 9 mm, then approximately 10% of CT colonography would require referral for optical colonoscopy. In a zero-sum budget environment with a fixed amount of dollars available for CRC screening, this would mean that CT colonography should be priced at 90% of the cost of optical colonoscopy. However, if lesion size of 5 mm or greater is set as the cutoff for referral, then 20% of CT colonoscopies would require referral, and screening CT colonography should be priced at 80% of the cost (professional + facility) of optical colonoscopy. Determining the optimal time interval and threshold for referral will be critical to the adoption of and payment for CT colonography.

Further, it remains unclear as how to make CT colonography cost-effective. Do we confine its use to populations with a low prevalence of lesions, where the need for follow-up optical colonoscopy is less likely? How do we identify people with a low pretest probability of cancer? Is CT colonography best utilized in patients with prior normal colonoscopy? Would it best serve men in their early 50s who have been traditionally resistant to optical colonoscopy? Again, no protocol has been established.

Other Barriers to Use

In the National CT Colonography Trial, training was a very important component. CT readers were required to have read at least 500 cases or undergo 10 days of training. All of the readers were required to take a certified examination, in which they had to successfully detect at least 90% of adenomas 1 cm or larger in 50 cases in order to pass. More than half of the readers had to undergo additional

training and retake the examination in order to pass. Gastroenterologists will need to be aware that if they envision performing the CT reading themselves, initial training and ongoing proctoring will be essential. Furthermore, with three-dimensional reading times of over 25 minutes for screening CT colonography, will radiologists and gastroenterologists take the time to perform these studies when other procedures are potentially more lucrative?

Up to this point, CT imaging has not been a service that could be performed in an ambulatory surgical setting. In the 2008 Ambulatory Surgical Center (ASC) Proposed Rule, Medicare proposed to revise the definitions of “radiology and certain other imaging services” when their provision is integral to a covered ASC surgical procedure. Effective beginning in 2008, the revised ASC payment system will cover a greater variety of surgical procedures performed in an ASC and make separate payments (outside the ASC composite rate) for certain integral radiology services performed in the ASC in conjunction with a surgical procedure immediately before, during, or immediately after the surgery. The Centers for Medicare and Medicaid Services (CMS) has included CT colonography, diagnostic (code 0067T), as a proposed ASC-covered ancillary service integral to a covered surgical procedure. Does this change mean that a CT scanner can be installed in the ASC?

As gastroenterologists evaluate whether to purchase or lease a CT scanner, they will also need to decide whether to install it in their office, in a free-standing, diagnostic-center setting, or in their ASC. Do they “go it alone” or partner with their hospital or an imaging vendor? Each of these decisions may engender a whole series of regulatory and reimbursement questions, depending on state laws and policies of individual insurers. Some insurers, such as United Healthcare, have required that beginning in 2008, all imaging centers in their network have accreditation. Other insurers, such as Highmark Blue Cross/Blue Shield, have specific criteria regarding the number of services an accredited imaging facility must offer and the times it is open in order to be a participating provider in their network.

CMS, in the 2008 Medicare Physician Fee Schedule Proposed Rule, proposed prohibiting physicians and practices from marking up an outside supplier’s net charge for a diagnostic test to the Medicare program. Notably, this markup prohibition applies regardless of whether the diagnostic test is purchased outright from the supplier or the practice is billing Medicare pursuant to a reassignment from the supplier. The proposed rule applies to both the professional and the technical components of the services. The only exception to this anti-markup rule is for full-time employees. If finalized, this proposal will remove

virtually all economic incentives for physician practices to bill Medicare for the professional component of diagnostic tests not performed by full-time employees of the practice, which is commonly done through the use of the Stark physician services exception. Under the proposal, the practice will not be able to recover from Medicare the overhead practice expense of interpretations performed in the practice’s facilities by part-time or independent contractor physicians. Consequently, practices that currently utilize part-time or independent contractor radiologists for the interpretation of diagnostic imaging services may decide to discontinue billing Medicare for such interpretation services or employ, if feasible, a radiologist on a full-time basis.

The bottom-line question for gastroenterologists becomes “what business are you in? Are you in the endoscopy business, or are you in the cancer detection and prevention business?” Some gastroenterologists may choose the traditional mindset of endoscopic procedures while attempting to remain oblivious to reductions in ASC facility fees and potential threats to colonoscopy reimbursement looming on the horizon. Others may decide to embrace a multidiscipline model of digestive healthcare, which may require the provision of comprehensive colorectal cancer screening incorporating all diagnostic modalities.

Future Directions

A variety of new business models and new business ventures will arise from the eventual integration of CT colonography into the CRC screening process. A question of primary importance to gastroenterologists is whether the volume of their practice will be large enough to support acquisition of CT imaging equipment. The corollary question is one of who is best positioned to read the scans. Gastroenterologists should be able to translate their knowledge of the endoscopic appearance of colorectal disease to CT colonography, following formalized training in CT physics, use of intravenous contrast, CT colonography interpretation and image manipulation, and CT colonography performance characteristics. CT colonography interpretation should include review and interpretation of at least 75 cases with endoscopic correlation.

Some practices may decide to support a full-time gastroenterologist devoted to reading CT colonography images, whereas others may enter into collaborative relationships with radiologists. When contemplating such decisions, the potential impact of CRC screening modalities, including stool DNA, self-propelling colonoscopes, and colon capsule endoscopes, as well as other modalities in development, must be considered.

Dr. Brill is the Chair of the AGA Institute Practice Management and Economics Committee, is the AGA Institute representative to the ASGE Practice Management Committee, is a member of the Board of Directors of the American Board of Quality Assurance and Utilization Review Professionals, Inc., and is on the Advisory Task Force of the National Transitions of Care Coalition. Dr. Brill has participated in Advisory Boards as a consultant to Given Imaging, Ethicon Endo-Surgery, The SmartPill Corporation, Kimberly-Clark Corporation, GI View Ltd., Colon Health Centers of America LLC, the Technion Research and Development Foundation, Ltd., and Early Bird Alert, Inc.

Suggested Reading

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