Radiology

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Building a CT Colonography Program: Necessary Ingredients for Reimbursement and Clinical Success[1]

Since its inception in April of 2004, the computed tomographic (CT) colonography clinical program at our institution has rapidly grown into a bustling viable enterprise. This editorial will detail our philosophies and actions in building a successful CT colonography program, which has already become an integral part of colon cancer screening at our center. The concept of success in this editorial refers to the following: *(a)* the ability to provide noninvasive yet effective colon cancer screening through the use of CT colonography; *(b)* the ability to interweave CT colonography into an already established optical colonoscopy program while maintaining cooperation and collegiality with gastroenterology colleagues; *(c)* the ability to provide a patient-friendly and seamless service for colorectal screening, including same-day polyp removal with optical colonoscopy, if needed; and *(d)* the ability to receive third-party reimbursement for screening CT colonography.

The factors necessary for success can occur at various levels. Broadly, there is a national level at which the current hurdles of demonstrating uniform clinical efficacy and addressing the continued resistance to reimbursement predominate. The local level relates to the milieu of hospitals and third-party payers that shapes the regional health care environment. Finally, there is the institutional level, at which equipment, personnel, hospital administration support, and clinical colleague relationships are critical. This editorial will deal with each of these three areas, taking note that the individual practitioner has more direct influence at the local and institutional levels. We will also provide a brief update on the current status of our CT colonography clinical program.

National Level

While there are fairly consistent national guidelines regarding the benefits of colorectal cancer screening in general, particularly with optical colonoscopy, there is not uniform agreement about the effectiveness of CT colonography. This is largely due to the current variability that exists regarding the methodology of the procedure (1,2), which has resulted in widely disparate performance characteristics in the low (polyp) prevalence setting (3–6). In comparison, optical colonoscopy is well established, reasonably consistent, and used by formally trained examiners.

CT colonography remains a rapidly evolving technology with considerable variability in terms of patient preparation approaches, finding interpretation, and software visualization techniques. Because of this variability, most national professional societies and advocacy groups, such as the American Cancer Society, have been unable to issue blanket statements in support of CT colonography screening (7). Inconsistent clinical results are also reflected in health technology assessment reports from such groups as the Technology Evaluation Center of the Blue Cross/Blue Shield Association and the Hayes Technology Assessment Group, which continue to view CT colonography as investigational (8,9). Thus, it is unlikely that the Centers for Medicare and Medicaid Services will provide financial coverage for screening CT colonography in the very near future. In fact, the recent introduction of category 3 Current Procedural Terminology, or CPT, codes for tracking the number of CT colonography procedures performed (0066T for screening, 0067T for diagnostic) could result in reduced reimbursement for diagnostic examinations for which there previously was payable coding (10). Therefore, important hurdles that must be overcome on the path toward national acceptance of CT colonography as an effective screening option include the current heterogeneity in methodology and the perception of mixed performance results.

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P.J.P. has a patent pending on the CT colonography bowel preparation described in this article.

Local Level

Because of the rather bleak outlook in the near term for CT colonography reimbursement at the national level, we undertook a more "grass roots" approach at the local level. Dane County, Wisconsin has a heavy distribution of locally owned managed care organizations (MCOs). There are a relatively small number of insured residents who are covered under a traditional indemnity insurance product. Therefore, decisions to reimburse providers for CT colonography screening are made by the MCOs. The fundamental purpose of an MCO is to collect premiums from purchasers (ie, employers, individuals, and the government) and to add value by providing management services so the purchaser can have either better or cheaper health outcomes for their premiums. This requires objective monitoring of health care service use. One of the principal management methods used by MCOs is technology assessment. The goal of this assessment is to review the available evidence to determine which technologies will result in desired health outcomes and in which populations and at what cost.

On the basis of a review of the clinical trial results published in the *New England Journal of Medicine* (3) and a formal presentation by the first author (P.J.P.) to the medical directors, one of the local MCOs (Physicians Plus Insurance) in Dane County determined that the specific technique used by this author was indeed comparable to optical colonoscopy in terms of effectiveness in the detection of clinically important colon polyps. A decision was made to approve reimbursement for this specific method of CT colonography, including both screening and diagnostic examinations (11). The decision of which specific screening method to use—CT colonography or conventional colonoscopy—was left to the patients in consultation with their physicians. Despite the fact that coverage for an additional screening option would probably lead to greater resource use, it was determined that this was an excellent use of premium dollars.

Additional MCOs in the area have since come to the same conclusion and now also provide coverage for the colorectal cancer screening procedure performed at the University of Wisconsin (11). To our knowledge, no other program to date has achieved similar third-party coverage for screening CT colonography. Furthermore, we are currently in active discussions with our local Medicare carrier medical director to obtain formal local coverage for diagnostic CT colonography; a decision by Medicare to cover screening would require national action.

There were additional factors that may have had some influence on these MCO coverage decisions. One factor was the long queue for screening optical colonoscopy (12), which was due to a combination of high local demand for screening and limited capacity. Another factor was the obvious need for increased patient compliance to colorectal cancer screening recommendations, particularly to encourage involvement among those who were reluctant to undergo optical colonoscopy. Finally, clear demonstration of the cooperative spirit and commitment among the radiologists and gastroenterologists involved in the project appeared to have a positive effect.

Institutional Level

The individual radiologist interested in providing CT colonography screening can have the most influence at this level. Close attention to many seemingly unrelated facets is needed for the successful implementation of a CT colonography program. These facets include proper equipment and technique, open support from hospital administrators, a dedicated program coordinator, and buy-in from clinical colleagues.

Equipment and Technique

The basic technical components that need to be considered for performing CT colonography have perhaps received the most attention to date since they represent a first step toward feasibility. These components include a multi–detector row CT scanner, a colon preparation technique, a colon distention technique, and a CT colonography software system. In actual practice, these technical factors merely scratch the surface of the challenges encountered in program implementation.

Although a multi–detector row CT scanner is necessary to achieve acceptable three-dimensional (3D) image quality, a four-channel scanner will probably suffice. This is partly because the gas-filled colon is a relatively static and forgiving target but also because the polyps that are relevant for reporting generally measure at least 5 mm in diameter. Therefore, a 4×2.5-mm detector configuration can be sufficient for successful examination (3). Of course, increased resolution will be possible with more detector rows, but in our experience, the actual difference in 3D image quality is not clinically apparent.

Robust colon preparation, including not only optimal fecal content removal but also some method of tagging any retained solid or liquid material, is important for accurate polyp detection (3,13). Patient preparation may begin as early as several days before the examination and range from minimal laxative use to full cathartic regimens that resemble those used for optical colonoscopy. Although the less vigorous preparations have not yet been adequately tested, at least some trade-off in polyp detection should be expected, and this approach may not enable same-day polypectomy, if it is needed. We have had great success in using a low-volume preparation protocol that starts the day before CT examination and in which three basic components are combined: sodium phosphate for catharsis, diluted 2% barium for solid stool tagging, and an ionic water-soluble contrast agent for fluid opacification. For patients with substantial renal or cardiac disease, magnesium citrate is used as a substitute for sodium phosphate.

Colon distention may be achieved with either room air or carbon dioxide. The rate and degree of insufflation can be semiautomatic, controlled by the patient, or controlled by the CT technologist. At our institution, we are currently evaluating patient-controlled room air insufflation versus automated carbon dioxide delivery to determine if the latter approach offers advantages in terms of reproducible distention and patient comfort that are sufficient to offset its increased cost.

The choice of software for interpretation is a critical factor, the importance of which greatly outweighs that of the small differences among different multi–detector row CT scanners. Although the two-dimensional approach for primary polyp detection has essentially proved to be inadequate in the low-prevalence setting (4–6), we have found that a biphasic interpretation protocol that incorporates both two-dimensional and 3D polyp detection (with emphasis on the latter) can be used to achieve an accuracy in the detection of clinically important polyps that is on a par with that of optical colonoscopy (2). The use of this biphasic approach requires a software package that not only offers high-quality 3D endoluminal rendering but also enables facile and time-efficient interactive 3D navigation (14).

Some software systems provide automated segmentation and center-line determination for 3D fly through, which allow the radiologist to interpret findings without the assistance of additional technical staff. Most CT colonography software systems have not been validated for polyp detection in the screening setting and therefore have not been approved by the U.S. Food and Drug Administration for this indication (15). On the basis of our experience, third-party payers will demand some assurance of the clinical effectiveness of these software systems before agreeing to provide reimbursement coverage for the procedure. For most software systems, such information does not yet exist.

Hospital Support

From a purely business standpoint, reimbursed screening of otherwise healthy adults performed by using CT colonography represents "new business" to a hospital or practice that was previously untapped. Currently, only about half the individuals in the recommended screening population are being tested by any means, and only a fraction of these individuals are undergoing full optical colonoscopy (16). Furthermore, each year, millions more Americans turn 50 years old, the recommended age to begin undergoing routine colorectal screening. When a radiology practice already has a multi–detector row CT scanner in place, the capital investment for starting a CT colonography program is relatively minimal. Hence, our hospital administrators were easily convinced of the potential benefit of this program. Even before local third-party reimbursement was guaranteed, the hospital was committed to providing funding for a program coordinator position and to carving out dedicated CT slots for colorectal screening examinations.

Scheduling patients for screening CT colonography requires some extra care. Early examination times for this prepared and fasting population are an important consideration, particularly from the patient's standpoint. An early appointment time allows the patient to resume regular activities almost immediately, which is a clear benefit compared with the scheduling limitations associated with optical colonoscopy. It should also be noted that this patient population is well suited for treatment at offsite outpatient imaging centers since screening CT colonography is a nonenhanced examination for typically healthy adults, many of whom may prefer to avoid the hospital setting.

Because we provide the option of same-day or next-day polypectomy, the patient is kept on a nothing-by-mouth regimen after the virtual examination until notified of the study results. The turnaround time for interpretation is kept under 2 hours but is often less than an hour. An early examination also gives the gastroenterology department more flexibility for arranging optical colonoscopy, if needed. This dedication in turnaround time requires a substantial commitment from the interpreting radiologist because the interpretations of these examination findings become "wet reads."

We encountered a somewhat unexpected hurdle in providing outpatient access to the CT colonography preparation material. Not only was a prescription required, but also the combination of over-the-counter laxatives and prescription oral contrast agents was new to the outpatient pharmacies so the contrast agents were not routinely in stock. Fortunately, our institution had a dedicated pharmacy section that was able to assemble the preparation into a convenient kit that included instructions and was dispensed to numerous satellite locations.

Program Coordinator

The central importance of a dedicated program coordinator during both the setup and the implementation phases of a clinical CT colonography program cannot be overstated. This person represents the linchpin of the program. Funding for our program coordinator position was supported by both the hospital and the medical school. The position was filled by a highly motivated registered nurse (D.A.J.) who was recruited from the expanding pool of nurses in our radiology department. This degree of expertise was helpful for understanding the medical issues involved in not only CT colonography but also optical colonoscopy. A highly skilled CT technologist also might have filled the position of program coordinator, if properly trained. The program coordinator must have strong communication skills to support frequent patient and referring physician interactions. The introduction phase of this new program required a great deal of time, which was focused on the education of patients, physicians, and the entire hospital staff. Although we certainly anticipated a challenge for our coordinator, the program has demanded even greater effort from this person than we expected. In the end, the program coordinator must share the vision of this worthwhile endeavor to endure the trials associated with the start-up period.

Clinical Colleagues

Initial discussions between clinically active physicians from the radiology and gastroenterology departments were started to incorporate CT colonography into the existing screening armamentarium. Once there was general agreement on the basic issues of program operation and interaction, the concept was then presented to the respective department heads and hospital administrators. At this level, preliminary discussions involving personnel, equipment, and payment could be addressed. Visible support from the gastroenterology department can provide needed credibility for a new CT colonography program. Although initial resistance from some gastroenterologists may be encountered, most of them will eventually agree that a comprehensive screening program involving both CT colonography and optical colonoscopy will ultimately benefit gastroenterology and radiology services and, most importantly, patients (17). The attraction of a less invasive "high-tech" examination such as CT colonography will draw people off the screening sidelines and thereby increase overall screening compliance. Furthermore, the potential shift in practice from diagnostic to therapeutic optical colonoscopy should result in overall increased gastroenterology procedure reimbursements and better use of more invasive and limited resources.

A critical source of debate between the radiology department and gastroenterology department staff members during early program development centered around the issue of polyp size thresholds. Although an in-depth discussion of this complex topic is beyond the scope of this editorial (1), the issue of what represents a clinically important polyp needed resolution. The radiology side generally favored a 10-mm size threshold for polypectomy referral, whereas gastroenterology favored a more aggressive approach because they remove all nondiminutive (>5 mm) polyps at optical colonoscopy and many gastroenterologists remove every lesion, regardless of its size.

After much discussion and interpretation of the literature (1,2,18), we decided on the following strategy with regard to CT colonography findings: All patients with polyps 10 mm or larger would be referred for optical colonoscopy for removal, excrescences 5 mm or smaller

would not be reported (in our report, we say that "CT colonography is not intended for the detection of diminutive polyps [those 5 mm or smaller], the presence or absence of which will not affect patient management decisions"), and patients with 6–9-mm polyps could opt to undergo either polypectomy or short-term CT colonography surveillance (initially in a closely monitored study protocol). The recommended CT colonography follow-up interval for patients without polyps larger than 5 mm was initially set at 5 years, pending further guidelines and outcomes data. It is important to note that this protocol was approved by our institutional review board, given the lack of precedents and the deviation from the gastroenterology standard of care. Furthermore, we obtain signed informed consent from all patients who choose noninvasive observation of nondiminutive polyps.

Support from gastroenterology colleagues is certainly helpful early on, particularly for facilitating the concept of combined colon care, but it is important to remember that most referrals for screening CT colonography will come from primary care providers. Therefore, it is this group of general practitioners that must ultimately appreciate the value of CT colonography for screening. This can be achieved through a variety of means, including medical literature review, grand rounds presentations, local media attention, and general word of mouth. If you can build a service-friendly and reliable CT colonography clinical program that receives financial reimbursements from third-party payers, the patients will definitely come.

Current Status

Since the inception of our program in April of 2004, the number of prescheduled slots for virtual colonoscopy screening has steadily risen. As of November 2004, we routinely perform eight to 10 screening examinations between 7:00 AM and 10:00 AM each day; this amounts to well over 100 examinations per month. The examination findings are read online by one of two experienced gastrointestinal radiologists (P.J.P., A.J.T.), who can then work in other clinical services for the remainder of the day. Demand has remained high, with many new requests each day and hundreds of patients now scheduled for screening months in advance. Less than 1% of our patients pay out of pocket for the procedures because most of the examinations are covered by a third-party payer. We are currently seeking additional ways to further expand our capacity to perform CT colonography.

Conclusion

The challenges facing widespread implementation of CT colonography programs for primary screening are substantial but certainly not insurmountable. Before a clinical CT colonography program can be successful, there are many seemingly disparate issues that must be adequately addressed. It is our hope that the lessons learned from the start-up of our CT colonography program will serve as a guide to others seeking to provide a similar service to their patients.

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