

Quality in Colon Cancer Screening



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Colorectal cancer is a leading cause of cancer death. Mortality can be reduced by screening asymptomatic individuals. Several different screening modalities have been recommended by experts. The ultimate effectiveness of a screening program depends on patient compliance and delivery of a high quality test at appropriate intervals. Each recommended screening program has significant quality control issues which can impair program effectiveness. This review describes the quality issues associated with colon cancer screening, and provides a framework for improving quality.

INTRODUCTION

Colorectal Cancer (CRC) is the second leading cause of cancer death in North America and Western Europe. Worldwide, there are more than 875,000 cases per year. In the United States in 2003, there were approximately 147,500 cases and 57,000 deaths, representing about 14% of cancer deaths (1).

Average-risk individuals have a 5% to 6% lifetime risk of developing CRC. Survival is directly related to stage at the time of diagnosis. If cancers can be detected at early stages, mortality can be reduced. CRC is usually asymptomatic until late stage disease. Therefore, the key to early discovery is the identification of high-risk patients before symptoms develop. There is now compelling evidence that population-based screening can reduce the mortality from CRC (2). Many expert panels have recommended screening for average risk individuals (2–5). Despite this evi-

dence, only 30%–40% of individuals over age 50 years old receive any of the recommended screening tests (6). Even among those who do receive screening, the quality of the screening programs is quite variable. Ultimately, the effectiveness of screening depends on 1) patient compliance and 2) the quality of the screening program. This paper will review the current screening recommendations, and discuss the quality control issues associated with each of the screening programs. The goal of this review is highlight important areas which require quality improvement.

FECAL OCCULT BLOOD TEST (FOBT)

Background

There is strong evidence from randomized controlled trials in large populations that FOBT can be effective. The studies demonstrate that among screened subjects, cancers are detected at an early, and more curable stage compared to patients who are not screened. Over time,

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this results in a significant reduction of mortality from CRC from 15%–33% (7–10). Further follow-up in the Minnesota study has also demonstrated that screened subjects have lower incidence rates of CRC—a benefit attributed to polyp detection and removal after the positive screening (11).

The clinical trials tested stool samples from three bowel movements obtained at home. Tests were interpreted by trained research staff. In the Minnesota study (7), FOBT slides were rehydrated with water before testing; in the European studies, rehydration was not used. Rehydration increases sensitivity and positivity rates at the expense of specificity. Most testing in the United States is with non-rehydrated FOBT. In the Minnesota study, subjects were assigned to annual or biennial testing; in Europe the tests were performed every two years. The Minnesota study demonstrated that annual testing is more effective than biennial tests, and the recommendations of multiple expert panels in the United States (2–4) are to perform annual tests.

Quality Issues

1. Programmatic repeat testing

The first, and most critical quality issue is the need for annual testing. Patient compliance with repeat testing is poor and may be due to several reasons. A negative test may offer reassurance to the patient that they do not have serious colon pathology. The VA Cooperative Study 380 (12) found that one-time FOBT detected only 24% of patients who had advanced neoplasia identified at screening colonoscopy (defined as adenoma 10 mm; adenoma with villous histology or high-grade dysplasia or invasive cancer). Therefore, a single negative test is often not informative. Program effectiveness requires repeat testing, which may detect curable lesions on a subsequent testing cycle. Therefore, health care providers who choose to use FOBT as the primary screening test, need to develop methods for recalling patients for annual repeat testing.

2. Technical issues

There has been much interest in factors which can contribute to false negative (Vitamin C) or false positive tests (red meat, peroxidase-containing vegetables, aspirin and other nonsteroidal anti-inflammatory

drugs). There is actually little evidence that these factors play an important role in program effectiveness. To the contrary, it has been suggested that requiring patients to adhere to diet and drug restrictions provides one more obstacle to patient compliance. Therefore, many experts no longer recommend that patients be asked to change diet or stop NSAIDs prior to testing.

3. Method of performing FOBT

Recent data from a survey of primary care providers highlights another important quality issue for FOBT. In a survey conducted by investigators from NCI, 25% of family practitioners and internists, and 65% of gynecologists used only a single digital exam FOBT as their primary form of screening (13). Several studies have suggested that the test may have a positive predictive value either more or less than a 3-day FOBT from home, but there are no data on actual sensitivity for cancer detection. There is considerable data justifying the need for the three-stool sample to improve the likelihood of detection, and reduce the likelihood of sample error. There is no evidence for effectiveness of single digital exam FOBT, and there are no recommendations for its use. Some have suggested that the single in-office test is better than no test, and that this may be the only way to achieve patient compliance. However, if the test is ineffective, it may provide both physicians and patients a sense of false confidence, and the patients will not have more effective recommended screening tests performed. This would be a disservice to patients. Unless and until there is data which justifies using digital exam FOBT, it should not be relied upon as the sole screening test. However, if the test is positive, it should be regarded as a true positive, and patients should undergo colonoscopic examination.

There has been considerable research evaluating different types of FOBT in an attempt to improve sensitivity and specificity. The addition of hydration (rehydration) increases sensitivity, but decreases specificity. Immunochemical tests which detect human heme are more specific, but less sensitive. Each method has tradeoffs when applied to population-based testing, and physicians should be aware of the differences. Although these issues are important, the other quality issues raised in this discussion are far

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more critical to the overall effectiveness of a FOBT screening program.

4. Evaluation of positive FOBT

The FOBT is used to identify patients who are more likely to have colon neoplasia. Patients who have a positive FOBT have a 3–4 fold increased risk of advanced colonic neoplasia compared to patients with a negative test (7,12). The positive predictive value increases with the number of positive test cards, but is still significantly high for patients who have only one of three positive cards. All expert panels recommend that patients with positive tests have a structural exam of the colon, preferably with colonoscopy. In clinical practice, up to 50% of patients with positive tests do not receive colonoscopy, rendering the FOBT screening program less effective. There are many reasons for not performing colonoscopy, including patient refusal and lack of physician referral. Nevertheless, this constitutes a major quality control issue for FOBT. Practices which use FOBT for screening, should emphasize the importance of colonoscopic follow-up for positive tests.

FLEXIBLE SIGMOIDOSCOPY (FS)

Background

Evidence for the effectiveness of sigmoidoscopy comes from case-control studies (14,15) which demonstrated a reduction in CRC mortality for cancers within reach of the sigmoidoscope. Specifically, the studies did not demonstrate a benefit for patients with proximal cancers. However, if patients who have index adenomas of any size undergo colonoscopy, there is evidence that up to 70% of patients with advanced neoplasia would be identified, including some patients with proximal advanced neoplasia (16,17). The current recommendations call for repeat testing at five years (2-5). The rationale for this interval is based on the presumed natural history of colon neoplasia, which requires many years for progression from normal mucosa to advanced lesion. A study from Indiana found that patients undergoing repeat colonoscopy (18) after five years had very low rates of advanced neoplasia. However, recent data from the PLCO study (19) have raised some questions about the interval. In

this large study, 0.8% of patients with a negative baseline test had advanced adenomas or cancer detected on a follow-up test within three years. However, the cancer incidence was only 0.06%.

Quality Control Issues

A recent review of quality issues highlighted several important domains, including training, bowel preparation, technique, lesion recognition, complications, reporting and equipment processing (20). I will focus on a few selected issues.

1. Patient compliance

Compliance with program testing may be a significant issue for FS. The test is performed without sedation, and many patients complain of some discomfort. There are no data available regarding compliance with repeat testing at five years. If program success depends on repeat testing, then developing systems which recall patients at five years intervals will be an important quality improvement indicator

2. Technical and training issues

In the PLCO study, exams were performed by primary care providers. Many exams were incomplete, with insertion depth of less than 50 cm in 10.3% of initial exams, and 13.3% of follow-up exams (19). The exams were considered inadequate in 12%-13% of examinations due to poor prep. In some cases, important lesions were not detected either due to inadequate insertion or poor prep. These data emphasize the importance of adequate training, and achieving a good bowel preparation for the examination.

3. Definition of positive test.

What findings at sigmoidoscopy should result in referral for colonoscopy? There has been controversy over the past 15 years about the importance of hyperplastic polyps or small adenomas < 10mm seen in the distal colon. The debate has centered around whether such patients have an increased risk of proximal advanced neoplasia. Two recent studies used screening colonoscopy in asymptomatic subjects to estimate the outcome of performing sigmoidoscopy (16,17). These

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studies, with more than 5,000 patients concluded that the finding of an adenoma of any size in the distal colon was associated with an increased risk of proximal advanced neoplasia, compared to patients who did not have polyps in the distal colon. Therefore these patients should be referred for complete colonoscopy.

There has been considerable controversy about the significance of hyperplastic polyps in the distal colon. Current evidence suggests that these lesions are non-malignant, and are not harbingers of serious proximal pathology. The two large screening colonoscopy studies found that the risk of advanced proximal neoplasia (defined as adenoma ≥ 10 mm, adenoma with villous histology or high-grade dysplasia, or invasive cancer) in patients with distal hyperplastic polyps was similar to patients who had no polyps in the distal colon. These studies concluded that if the only finding in the distal colon was a hyperplastic polyp, complete colonoscopy is not recommended. These recommendations have been endorsed by the multi-society panel (2).

Therefore, a key clinical decision may depend on the determination of histology of small distal polyps: if hyperplastic, no further evaluation is needed; if adenomatous, colonoscopy is recommended. Endoscopically, can we distinguish hyperplastic from adenomatous polyps? Although some characteristics, such as color, may be helpful, there are no reliable criteria that can discriminate a HP from an AP. Several studies have found that high-resolution chromoendoscopy with contrast agents and magnification can distinguish HP and AP with excellent sensitivity and specificity (21). Staining with indigo carmine or methylene blue can highlight subtle mucosa surface patterns. HP tend to have characteristic pit patterns which closely resemble the character of the surrounding normal mucosa. AP have surface grooves or sulci which are distinctly different than the normal mucosa pit pattern. Despite the success of these early studies, few endoscopists incorporate chromoendoscopy into their practice because of the additional time required to stain, and then examine the colon segment. Even with sensitivity of more than 80%, these methods are not a perfect replacement for biopsy and histologic evaluation.

Therefore, another quality control issue for sigmoidoscopy rests on the decision to obtain a biopsy of small polyps to determine histology. Since the decision

to proceed with colonoscopy depends on histology, small polyps encountered at sigmoidoscopy should be biopsied.

IMAGING STUDIES

Background

Barium enema is included among the recommended screening tests for CRC. There are no effectiveness data in screening populations. The National Polyp Study found that barium studies identified less than 50% of patients with polyps or lesions >10 mm (22). Other imaging studies, using helical computer tomography (CT colonography or virtual colonoscopy) or magnetic resonance imaging (MRI) are still experimental, and not currently recommended.

Quality Issues

Recent studies of CT colonography highlight several important quality issues. There is significant inter-observer variability demonstrated in some but not all studies (22,23), which may reflect an evolving technology. CT colonography currently requires an excellent cleansing of the colon for an adequate exam. Poor bowel preparation can result in false positive interpretations. Future evolution of this technique may include labeling of stool, or using methods which can allow subtraction of stool density, such as magnetic resonance imaging. Technical aspects of test performance such as radiation exposure and imaging technique are still evolving, and improving.

COLONOSCOPY

Background

There are no clinical trials which have demonstrated the effectiveness of colonoscopy as a primary screening test. Nevertheless, there is considerable indirect evidence. The FOBT trials used colonoscopy to evaluate positive tests, and it was colonoscopy which diagnosed tumors and led to detection and removal of

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polyps. The sigmoidoscopy case-control studies demonstrated a benefit for the portion of the colon examined. Intuitively, if more colon is examined, the benefit may be greater. The VA Cooperative Study #380 compared the detection rate of advanced neoplasia based on extent of distal exam (16). If the distal exam reached the sigmoid-descending junction, 70% of patients with advanced neoplasia were detected; if it reached the splenic flexure, 80% of patients would have been identified. A case-control study in the Department of Veteran Affairs found that patients exposed to colonoscopy had lower mortality from CRC (25). And finally, the National Polyp Study demonstrated that patients who had colonoscopy with complete polypectomy, had a 76%–90% reduction in expected rates of CRC over the next six years (26).

Quality Issues

1. Training and Performance issues

There are few data on what constitutes adequate training for colonoscopy. Many experts suggest that competency cannot be assessed until trainees have completed at least 200 examinations, many of which should include polypectomy. If colonoscopy is performed by undertrained providers, the accuracy and safety of the exam may not reach recognized benchmarks. Rex, et al (27) examined the records of patients diagnosed with colorectal cancer in Indiana, and asked whether these patients had a prior colonoscopy exam in the year prior to diagnosis. They presumed that the tumor was most likely present during that exam. There was a higher rate of “missed” lesions by non-gastroenterologists. This study emphasizes the need for appropriate training, regardless of specialty.

The GI Professional Organizations (ACG, AGA, ASGE) in collaboration with the ACP-ASIM have published a quality control document for colonoscopy, describing proposed standards for endoscopic reporting and quality improvement (28).

The Task Force noted that cecal intubation rates above 90% are consistently achieved by experienced colonoscopists, and that rates above 90% are a goal of training programs. Higher rates (97%–99%) have been achieved in screening studies of asymptomatic subjects. Therefore, the task force proposes that a bench-

mark for cecal intubation of 90% of all cases, and of 95% for screening cases. They also recommend that the endoscopic report note the finding of cecal landmarks (ileocecal valve and appendiceal orifice) in all cases.

The Task Force focused on endoscope withdrawal, which is the crucial portion of the exam, during which pathology is found and removed or biopsied. Rapid withdrawal is associated with missed lesions. Therefore, the Task Force recommends that at least six to 10 minutes should be spent during the withdrawal phase.

Colonoscopy, even in experienced hands is not perfect and some important lesions will be missed. In two studies, different endoscopists performed back-to-back colonoscopy exams, the miss rate for serious pathology was very small (29,30). However, in clinical practice, it is probably more common. In a recent study of virtual colonoscopy, the investigators also assessed the sensitivity and specificity of colonoscopy (24). CT colography was performed first, and lesions noted for each segment of the colon. Then colonoscopy, segment by segment was performed. The endoscopist was not aware of the CT findings. After completing the exam of a segment, the colonoscopist was told about the CT findings. If pathology was seen on CT, and not on the initial colonoscopy, there was a second exam of the segment. If pathology was found on the second exam, the colonoscopy was considered falsely negative for that segment. Overall, the sensitivity of colonoscopy for detection of 10cm lesions was 88%. These data emphasize two important points. First, withdrawal time is a critical part of the exam, and slow withdrawal is advised. Second, colonoscopy will never be perfect, and patients should be informed that significant lesions may be missed.

2. Complications

Colonoscopy is associated with the greatest risk of complications among the screening test options. Many of the complications occur in patients with polyps who undergo polypectomy. In the VA Cooperative Study #380, 3,196 patients had screening colonoscopy. The risk of major complications, defined as death, perforation, bleeding requiring intervention, and hospitalization was 0.3% (31). Perforation rates range from 0.5–2 per thousand (28). Perforation is due to mechanical rupture of the colon from instrument passage or air, or

occurs at polypectomy with cautery. The expected rates of major bleeding is less than 1%. Cardiopulmonary complications account for about 50% of all adverse events associated with colonoscopy, and many are related to sedation. Continuous quality improvement programs should carefully monitor and review all serious complications. These data highlight the dangers of colonoscopy and the importance of adequate training.

3. Testing Interval

Expert panels have suggested that colonoscopy screening could be performed at 10 year intervals if the baseline exam is negative (2–4). This recommendation is based on the usual natural history of colon neoplasia, and from a case-control study using sigmoidoscopy which found a protective effect for up to 10 years in the portion of the colon examined (14). Rex, et al (18) performed a second colonoscopy at 5.5 years in a group of patients with negative baseline colonoscopy. Only one of 154 patients had a polyp greater than 1cm, and no patient had cancer. However, the recent report by Schoen, et al (19) introduces a cautionary note. After a baseline sigmoidoscopy, six of 1,292 patients had cancer discovered in the distal colon at three years, and 72 patients had an advanced adenoma. Although some of the “new” lesions were probably present, but undetected, on the baseline exam, some may have been “fast-growers.” Up to 15% of colorectal cancers have microsatellite instability, associated with mutations of mismatch repair genes. These patients may develop polyps which progress more rapidly to malignancy. Future studies are needed to identify risk factors associated with early interval cancers.

SUMMARY

Quality control is an essential element of CRC screening programs. Each element of program quality can have a large impact on the effectiveness of the screening program. For FOBT, key quality control issues are 1) collection of 3-stool sample; 2) evaluation of positive tests with structural examination of the colon; 3) compliance with repeat testing if tests are negative. For flexible sigmoidoscopy, QC issues are 1) completeness of examination; and 2) follow-up of positive screening (* adenoma) with colonoscopy. For colonoscopy, QC

issues are 1) training; 2) defining and achieving performance benchmarks; and 3) complications.

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