The Findings and Impact of Nonrehydrated Guaiac Examination of the Rectum (FINGER) Study

A Comparison of 2 Methods of Screening for Colorectal Cancer in Asymptomatic Average-Risk Patients

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Background: Testing stool for occult blood at the time of digital rectal examination (DRE) has been discouraged because it is thought to increase the number of false-positive test results.

Objective: To compare the diagnostic yield of colonoscopy and the cost per cancer detected in asymptomatic patients with a positive fecal occult blood test result obtained by DRE with that obtained from spontaneously passed stool (SPS) samples.

Methods: We reviewed the medical records of consecutive asymptomatic patients at average risk for colorectal cancer who were referred for colonoscopy to evaluate a positive fecal occult blood test result obtained by DRE (n = 282) or SPS samples (n = 390). The cost of colonoscopy was estimated by adding the physician fee under Medicaid reimbursement, the facility fee for endoscopy, and the pathology fee for the biopsy specimens.

Results: During the 5-year study period, 672 patients were evaluated and a colonic source of occult bleeding was identified in 145 patients (21.6%). The predictive value of a positive fecal occult blood test result (22.0% vs 21.3%, \( P = .85 \)) and the cost per cancer detected ($7604.80 vs $7814.54) were no different in the DRE and SPS groups, with carcinomas being detected in 11.7% and 11.3% of patients, respectively.

Conclusions: Testing stool for occult blood at the time of DRE does not increase the number of false-positive test results or the cost per cancer detected in asymptomatic patients at average risk for colorectal cancer. In this patient population, all individuals should be evaluated by full colonoscopy regardless of the method of stool collection.

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Screening for fecal occult blood has been shown to reduce mortality from colorectal cancer, the second leading cause of cancer death in the United States. Because 70% to 80% of colorectal cancers are diagnosed in “average-risk” patients, the American Cancer Society recommends annual fecal occult blood testing (FOBT) of stool samples in all patients aged 50 years or older using 3 specimens obtained from spontaneously passed stools (SPS). To decrease the number of false-positive FOBT results, patients are placed on dietary restrictions, and nonsteroidal anti-inflammatory drug (NSAID) and aspirin use is discontinued 1 week before testing. Despite these recommendations, clinicians often test stool samples for occult blood at the time of digital rectal examination (DRE). Although widely practiced, this screening method has been discouraged because it is thought to increase the number of false-positive FOBT results.

In clinical practice, asymptomatic individuals with a positive FOBT result obtained by DRE are often referred for a colonoscopic evaluation. To date, there are almost no data on the diagnostic yield of colonoscopy in asymptomatic patients with a positive FOBT result obtained by DRE. The aims of this study were to compare the diagnostic yield of colonoscopy in patients with a positive FOBT result obtained by DRE with that obtained by SPS sampling and to determine the cost of identifying a source of occult gastrointestinal bleeding by colonoscopy in these 2 groups of patients.

RESULTS

During the 5-year study period, 672 asymptomatic average-risk patients with...
PATIENTS AND METHODS

PATIENTS

Consecutive asymptomatic patients older than 50 years at average risk for colorectal cancer with a positive FOBT result obtained by DRE or SPS sampling who were referred to the gastroenterology service at Bellevue Hospital Center, New York, NY, between January 1992 and January 1997 were identified. Patients were excluded from this study if they had any abdominal signs or symptoms. Average-risk individuals were defined as patients who did not have a history of colon polyps or colorectal cancer, a family history of colorectal cancer, or inflammatory bowel disease.

DATA COLLECTION

Data on each patient, which were collected by means of a review of endoscopy records, patient charts, and pathology reports, included age, sex, race, location at the time of endoscopy (inpatient vs outpatient), presence of comorbid illness, history of peptic ulcer disease, history of upper or lower gastrointestinal hemorrhage, presence of anemia, and use of alcohol, aspirin, NSAIDs, anticoagulants, or tobacco. Comorbid illness was defined as the presence of any of the following: cardiovascular disease (congestive heart failure, recurrent angiina, or endocarditis), pulmonary disease (pneumonia, pulmonary embolus, or chronic obstructive pulmonary disease), liver disease (acute hepatitis, chronic hepatitis, or cirrhosis), renal disease (creatinine level >= 177 µmol/L [2 mg/dL]), neurologic disease (meningitis or central nervous system disease with loss of independence), metastatic cancer, or the presence of a systemic bacterial or fungal infection. Anemia was defined as a hemoglobin level of less than 140 g/L in men or less than 120 g/L in women. Fecal occult blood testing was performed by testing 2 samples from each of 3 SPS or 1 specimen obtained during DRE using commercially available test kits (Hemoccult II; SmithKline Diagnostics Inc, San Jose, Calif) without rehydration. The presence of occult blood was identified when a positive test result was noted on at least 1 slide.

ENDOSCOPY

All colonoscopic examinations were performed by gastroenterology fellows with an experienced faculty member in attendance. Informed consent was obtained from each patient before every procedure. All endoscopic abnormalities were noted, and multiple biopsy specimens were obtained from each one. All polyps were removed whenever possible. No major complications directly related to endoscopy were noted. Lesions that were considered a source of occult gastrointestinal blood loss included: adenomatous polyps greater than or equal to 1 cm in diameter, carcinoma, active colitis or inflammatory bowel disease, colonic ulcers greater than or equal to 1 cm in diameter, and multiple vascular ectasias. Hemorrhoids and diverticula were not considered a source of occult gastrointestinal blood loss.

STATISTICAL ANALYSIS

The diagnostic yield of colonoscopy in patients with a positive FOBT result obtained by DRE was compared with that in patients who were found to have occult blood in SPS samples. The cost of identifying a source of occult bleeding, cost per neoplasm, cost per adenoma, cost per adenoma greater than or equal to 1 cm in diameter, and cost per cancer detected by these 2 methods of screening were calculated. Continuous variables were compared using a t test or a nonparametric test, as appropriate. Categorical variables were compared using the Fisher exact test. A 2-tailed P value of less than .05 was considered statistically significant. All data are expressed as mean ± SD. Statistical analysis was performed using a commercially available software package (SPSS version 7.5 for Windows; SPSS Inc, Chicago, Ill.).

A positive FOBT result were evaluated by colonoscopy. The patient characteristics are shown in Table 1. Patients referred for a positive FOBT result obtained by SPS sampling were more likely to be outpatients than those who were tested during DRE. The remaining demographic and clinical characteristics were similar in both groups of patients. A colonic source of occult gastrointestinal bleeding was identified in 145 patients (21.6%). The predictive value of a positive FOBT result was no different between those who were tested by DRE and those who had occult bleeding detected by SPS sampling (22.0% vs 21.3%, P = .85). The lesions detected by colonoscopy are shown in Table 2. The number of patients with neoplastic lesions (adenoma or adenocarcinoma), adenomas, adenomas greater than or equal to 1 cm in diameter, and adenocarcinoma were similar in both groups of patients. Also, 7 patients had vascular ectasias, 3 had ulcerative colitis, and 1 had Crohn disease. Five of the 7 patients with vascular ectasias had multiple lesions located in the cecum and ascending colon; the remaining 2 patients had isolated lesions in the sigmoid colon. Of the 3 patients with ulcerative colitis, 1 had pancolitis, 1 had proctosigmoiditis, and 1 had disease limited to the rectum. The patient with Crohn disease had involvement of the ileum and proximal colon. Lesions that were thought not to be a cause of occult bleeding included hemorrhoids (125 patients [18.6%]), diverticulosis (49 patients [7.3%]), and both hemorrhoids and diverticulosis (37 patients [5.5%]). The findings of colonoscopic examination were normal in 249 patients (37.1%).

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The average cost of performing colonoscopy was $885.12 per patient, and there was no difference in cost between the DRE and SPS groups ($889.92 vs $881.64). The cost of identifying a colonic source of occult gastrointestinal bleeding is shown in Table 3. The cost of detecting an adenoma equal to or greater than 1 cm in diameter was slightly higher in the DRE group, while the cost per adenocarcinoma found was slightly higher in the SPS group. However, these differences were not substantial.

Numerous factors compromise the effectiveness of screening for colorectal cancer with FOBT. In structured rigorous trials, the rate of return of screening guaiac cards has ranged from 40% to 68%. Furthermore, this estimate decreases to approximately 30% in community screening programs, with patient education, aversion to stool sampling, and the rigor of the recruitment effort all affecting patient compliance. Even if patients are willing to collect multiple stool samples, adherence to dietary restrictions and abstinence from NSAIDs and aspirin are often less than ideal. During the DRE, which is an established part of the physical examination, many physicians obtain stool samples to perform FOBT, as this may be the only opportunity to screen for colorectal cancer. However, the use of FOBT of stool samples obtained by DRE to screen for colorectal cancer is controversial.

In an editorial on this subject, Longstreth describes the testing of stool samples obtained by DRE for fecal occult blood as a “knee-jerk” procedure that has little sensitivity or specificity in screening for colorectal cancer. He attributes the limitations of this screening method to hemorrhoidal trauma by DRE, the lack of control over the use of medications such as NSAIDs or supplements such as ascorbic acid, the fact that only a single specimen is obtained, and interpretation of the test results by a physician rather than by an experienced laboratory technologist.

In a retrospective study of 202 patients who underwent a DRE and stool guaiac test on admission to the hospital, Gomez and Diehl found that the results of clinically indicated tests were positive more often than those of routinely performed tests (35% vs 11%). Based on these findings, they concluded that FOBT performed during physical examination should be reserved for patients with clinical indications such as symptoms of acute or chronic gastrointestinal bleeding, anemia, weight loss, or change in bowel habits.

To our knowledge, there are no studies demonstrating that the sensitivity and specificity of FOBT of stool samples obtained by DRE are less than those of SPS sampling. In an earlier study, Eisner and Lewis reviewed the records of 270 patients who underwent colonoscopy for a positive FOBT result obtained at the time of DRE (144 patients) or after testing of 3 SPS samples (126 patients). In this mixed population of symptomatic and asymptomatic patients, the authors found a similar frequency of colonic abnormalities with both stool collection methods and no statistically significant differences in the rates of detection of adenomatous polyps or colon cancers.

In another study, Brint et al retrospectively evaluated 185 asymptomatic patients who underwent colo-
noscopy for a positive FOBT result obtained by DRE and found neoplastic lesions in 28% of them. Based on these findings, they concluded that screening for colorectal cancer by DRE does not increase the rate of false-positive results, and that positive test results should prompt a structural evaluation of the colon. Interestingly, a recent study found that the likelihood of a gastrointestinal lesion being detected was significantly higher in patients who had fecal occult blood detected during DRE than among those who had a positive test result obtained by the traditional method of testing SPS samples.\textsuperscript{17}

In the current study of 672 asymptomatic patients at average risk for colorectal cancer, we found the predictive value of a positive FOBT result obtained by DRE to be no different from that obtained by SPS sampling (22.0% vs 21.3%). Furthermore, there was no difference in the number of adenomas, adenomas larger than 1 cm in diameter, or carcinomas between these 2 groups of patients. To our knowledge, this is the first study to compare these 2 methods of screening in a cohort of asymptomatic patients at average risk for colorectal cancer.

Although other investigators have suggested that testing stool for fecal occult blood at the time of DRE may increase the number of false-positive test results,\textsuperscript{9} we found no difference between these 2 methods of screening for colorectal cancer. One possible hypothesis to explain this lack of difference is that DRE does not cause a false-positive test result and that there is truly no difference between these 2 methods. Alternatively, patients who were found to have fecal occult blood present when SPS samples were tested may have been noncompliant with dietary, NSAID, and aspirin restrictions. Noncompliance may have increased the number of false-positive test results in the SPS group, resulting in a positive predictive value that was similar to that of the DRE group. However, this latter hypothesis would be impossible to validate in a retrospective study.

In the present study, 527 patients (78.4%) did not have a colonic source of occult gastrointestinal bleeding identified. The low predictive value of a positive FOBT result in our patient population (21.6%) is a well-described limitation of screening for colorectal cancer with guaiac-based tests.\textsuperscript{14} Since the positive predictive value is highly dependent on the prevalence of disease in the population studied, it is not surprising to find a high number of false-positive test results in a cohort of asymptomatic patients. In addition to the test result being truly false-positive, colonic lesions may have been missed during our endoscopic examination. Alternatively, the positive FOBT result may have detected occult bleeding from a site in the gastrointestinal tract proximal to the colon. Indeed, we,\textsuperscript{18} and others\textsuperscript{17,10-23} have found a considerable number of patients with a positive FOBT result and normal colonoscopic findings who had lesions detected during upper gastrointestinal endoscopy.

The cost of screening for colorectal cancer with FOBT, including the cost of colon evaluation of positive test results, has been estimated to be approximately 1.2 billion dollars per year for the 60 million Americans older than 50 years.\textsuperscript{24} Testing of stool samples obtained at the time of DRE has been discouraged because this screening method is thought to increase the number of false-positive test results, thereby increasing the cost per cancer detected as well as the complications associated with unnecessary endoscopic procedures. However, in our study, we found the cost per adenoma larger than 1 cm in diameter ($8654 vs $7316) and the cost per cancer detected ($7605 vs $7815) to be unaffected by the method of stool collection. The cost per adenoma larger than 1 cm in diameter is similar to the cost per polyp ($8689) that has been reported in other studies.\textsuperscript{15} It is interesting to note, however, that the cost per cancer detected in the present study was less than half of that previously reported.\textsuperscript{13} Furthermore, colonoscopy did not result in any major complications in either group.

If our findings are confirmed in prospective studies, screening by DRE would have a positive impact on colorectal cancer screening. Testing stool samples obtained at the time of DRE may reduce the cost of screening because only 1 guaiac test kit would be needed instead of 3, and the amount of time that nurses and physicians spend with patients teaching them about dietary restrictions would be reduced substantially. More importantly, the number of patients who would be screened would increase from the current rate of approximately 30%\textsuperscript{11,14} to nearly 100% of patients who are seen by a physician (assuming that all physicians offer testing to their patients). This can potentially reduce the mortality from colorectal cancer considerably.

In conclusion, we found that FOBT of stool samples obtained by DRE does not increase the number of false-positive test results or the cost per neoplasm detected in asymptomatic patients at average risk for colorectal cancer. Although we do not recommend FOBT at the time of DRE as a routine method of screening for colorectal cancer, our data would suggest that in this patient population, a positive FOBT result should be evaluated by full colonoscopy. Prospective randomized studies comparing FOBT and SPS sampling are warranted to validate these findings before testing stool samples at the time of DRE can be routinely recommended.

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