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Accuracy of Screening for Fecal Occult Blood on a Single Stool Sample Obtained by Digital Rectal Examination: A Comparison with Recommended Sampling Practice

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Background: **Many expert panels recommend colorectal cancer screening for average-risk asymptomatic individuals older than 50 years of age. Recent studies have found that 24% to 64% of primary care providers use only the digital fecal occult blood test (FOBT) as their primary screening test. The effectiveness of a single digital FOBT is unknown.**

Objective: **To compare the sensitivity and specificity of digital FOBT and the recommended 6-sample at-home FOBT for advanced neoplasia in asymptomatic persons.**

Design: **Prospective cohort study.**

Setting: **13 Veterans Affairs medical centers.**

Patients: **3121 asymptomatic patients 50 to 75 years of age.**

Intervention: **2665 patients had 6-sample at-home FOBT and digital FOBT, followed by complete colonoscopy.**

Measurements: **We measured the sensitivity of digital and 6-sample FOBT for advanced neoplasia and the specificity for no neoplasia. We calculated predictive values and likelihood ratios for advanced neoplasia, defined as tubular adenomas 10 mm or greater, adenomas with villous histology or high-grade dysplasia, or invasive cancer.**

Results: **Of all participants, 96.8% were men; their average age was 63.1 years. The 6-sample FOBT and the single digital FOBT had specificities of 93.9% and 97.5%, respectively, as defined by studying 1656 patients with no neoplasia. Sensitivities for detection of advanced neoplasia in 284 patients were 23.9% for the 6-sample FOBT and 4.9% for the digital FOBT. The likelihood ratio for advanced neoplasia was 1.68 (95% CI, 0.96 to 2.94) for positive results on digital FOBT and 0.98 (CI, 0.95 to 1.01) for negative results.**

Limitations: **Most patients were men.**

Conclusions: **Single digital FOBT is a poor screening method for colorectal neoplasia and cannot be recommended as the only test. When digital FOBT is performed as part of a primary care physical examination, negative results do not decrease the odds of advanced neoplasia. Persons with these results should be offered at-home 6-sample FOBT or another type of screening test.**

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Many organizations and expert panels recommend colorectal cancer screening in average-risk asymptomatic persons older than 50 years of age (1–3). Randomized, controlled trials show that screening with fecal occult blood tests (FOBTs) can reduce both death from colorectal cancer and subsequent incidence of new cancer (4–9). These studies performed FOBT by having patients submit 2 samples from 3 stools obtained on 3 consecutive days for analysis. The expert panels recommend 6-sample FOBT to reduce the likelihood of false-negative results due to sampling error (1–3).

Recent studies have found that many primary care providers use FOBT as their primary screening test. However, the methods used to obtain stool samples vary greatly. In 24% to 64% of practices, a single digital rectal examination performed in the office is the primary method for obtaining stool for FOBT (10, 11). The presumed rationale for using an office-based test is to improve patient adherence. Previous studies have found that the positive predictive value of an office-based FOBT is similar to that of the standard 6-sample home test (12, 13). There are no data evaluating the sensitivity and specificity of office-based digital FOBT or its effect on mortality reduction in colorectal cancer (2). No previous studies performed colonoscopy in patients with negative results on office-based digital FOBT. Therefore, negative results on digital FOBT may falsely reassure both patients and physicians. If a single office-based digital FOBT is commonly used for colorectal cancer screening, it is important to understand the sensitivity and specificity of this strategy.

Our group previously reported the results of screening with colonoscopy in 2885 asymptomatic patients 50 to 75 years of age (14). The prevalence of advanced neoplasia was 10.6% in a predominantly male cohort of veterans. Ad-

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Context

Many physicians screen for advanced colonic neoplasia by testing the stool obtained from a digital rectal examination for occult blood.

Contribution

The authors performed fecal occult blood tests (FOBTs) on samples from digital rectal examination and did complete optical colonoscopy on 2665 average-risk asymptomatic adults. The sensitivity and specificity of digital FOBT for advanced colonic neoplasia were 4.9% and 97.1%, respectively. The positive and negative likelihood ratios were 1.68 and 0.98, respectively.

Implications

A negative result on a test for fecal occult blood in a digital rectal sample does not change the odds of advanced colonic neoplasia. Physicians should not rely on FOBT performed on a single sample of stool.

–The Editors

vanced colonic neoplasia was defined as an adenoma with a diameter of 10 mm or more, a villous adenoma (that is, ≥25% villous), an adenoma with high-grade dysplasia, or invasive cancer. Patients with intramucosal carcinoma or carcinoma in situ were classified as having high-grade dysplasia. Patients with more than 1 lesion were classified according to the most advanced disease stage. In that prospective study, the home-based 6-sample FOBT with rehydration yielded positive results in 24% of patients with advanced neoplasia (14). To our knowledge, no previous study has evaluated the sensitivity of digital FOBT. The primary aim of the current study was to compare the sensitivity and specificity of digital FOBT and recommended 6-sample FOBT in asymptomatic patients who had both types of FOBT and underwent complete screening colonoscopy regardless of FOBT results. We now report the test results in patients who had both types of FOBT, followed by a complete screening colonoscopy. Colonoscopy was performed regardless of positive or negative FOBT results.

METHODS

Patient Entry

Patients 50 to 75 years of age were randomly recruited from primary care clinics at 13 Veterans Affairs medical centers from February 1994 to January 1997. We also recruited patients referred for screening flexible sigmoidoscopy and those with a family history of colorectal cancer (14, 15). Patients were excluded if they reported symptoms of lower gastrointestinal tract disease, including rectal bleeding on more than 1 occasion in the previous 6 months, a marked change in bowel habits, or lower abdominal pain that would normally require a medical evaluation. Other exclusion criteria included any previous disease of the colon, structural examinations of the colon within the previous 10 years, and serious comorbid conditions that would increase the risk for colonoscopy. The current study sample includes all patients who had complete colonoscopy to the cecum and results from both 6-sample at-home FOBT and adequate digital FOBT (n = 2665). A central human subjects committee and local committees at each participating center approved the study protocol.

Procedures

Eligible patients had a complete physical examination by the study physician that included a digital rectal examination to identify rectal masses and obtain stool for FOBT. If adequate stool was present, FOBT was performed on a single sample by using guaiac-impregnated cards (Hemoccult II, SmithKline Beckman, Palo Alto, California). Since the digital FOBT sample was immediately developed by the study nurse, rehydration was not performed. In addition, patients were given Hemoccult II cards to collect 3 spontaneously passed stool samples before bowel preparation and colonoscopy. They also received a sheet of written dietary instructions advising them to restrict consumption of red meat, vitamin C, and aspirin before obtaining the samples, but adherence to these measures was not monitored. Each card contained 2 guaiac-impregnated windows, and fecal material from each stool sample was applied to 2 sites on the card, for a total of 6 samples per patient. The cards were returned on the day of the colonoscopy. After a drop of water was added (rehydration), the developer solution was applied. Trained study nurses interpreted the developed cards. In most cases, the endoscopist was not aware of the results of either FOBT. Patients who did not have a completed digital FOBT or who did not submit test cards were excluded from this analysis. All patients had complete colonoscopy to the cecum.

Histologic Evaluation

At colonoscopy, all visible polypoid lesions were removed or biopsied and sent to local pathology laboratories for processing. Results were interpreted by the local pathologist, a central pathologist, and, when there was disagreement, a third reviewing pathologist. None of the pathologists were aware of the other test results or interpretations. Patients were classified on the basis of the most advanced lesion detected during colonoscopy.

Statistical Analysis

The Veterans Affairs Cooperative Studies Program Coordinating Center at Perry Point, Maryland, served as the central statistical and data management coordinating center. The statistical analysis detailed here is based primarily on descriptive statistics, including means and SDs for continuous variables as well as the calculation of rates and proportions for categorical data. The performance characteristics of the diagnostic screening strategies were evaluated by calculating sensitivity and specificity according to the standard definition; these results are presented

separately by histologic category, along with corresponding 95% CIs. We also included positive and negative predictive values and likelihood ratios with corresponding 95% CIs for both positive and negative FOBT results; patients who had no advanced neoplasia were compared with those who had advanced neoplasia. All data management and statistical analysis were performed with SAS software, version 6.12 (SAS Institute, Inc., Cary, North Carolina).

Role of the Funding Source

This study was funded by the Department of Veterans Affairs Cooperative Studies Program (VACSP) and was conducted according to VACSP guidelines. In the VACSP, investigators propose, design, and conduct studies. The VACSP approved the design and conduct of this study and reviewed and approved the manuscript before submission.

RESULTS

Of 17 732 persons who were screened for study inclusion, 3196 met the criteria for enrollment. A complete examination of the colon was performed in 3121 eligible persons. Of these, 2885 had 6-sample at-home FOBT results (14). A total of 2665 (92.4%) had both digital FOBT and 6-sample FOBT completed before colonoscopy and are included in this analysis (**Figure**). The mean age (±SE) of the study group was 63.1 ± 0.14 years; 96.8% were men, and 14% reported having a first-degree relative with colorectal cancer. The demographic and pathologic characteristics of the 220 patients who were excluded on the basis of inadequate FOBT data are shown in **Table 1**. Reasons for incomplete FOBTs were failure to return the home-based cards or inadequate fecal material in the rectum at the time of digital examination. Included and excluded patients were similar except for a younger mean age (mean of 1.4 years younger) in the excluded group.

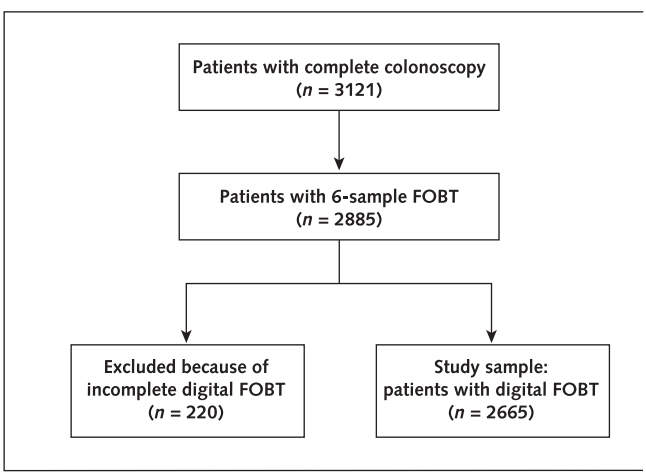
Of the 2665 patients, 1218 (45.7%) had no polypoid lesions found at colonoscopy. In 438 patients, the most advanced lesion found was a hyperplastic polyp, a nonadenomatous polyp, or a polyp with normal characteristics on biopsy. The FOBT results are shown in **Table 2**. Among the 1656 patients without adenomas, digital FOBT yielded positive results in 41 (specificity, 97.5% [95% CI, 96.8% to 98.3%]) and at least 1 window of the 6-sample FOBT yielded positive results in 101 (specificity, 93.9% [CI, 92.7% to 95.1%]). In 725 patients, the most advanced lesion was 1 or more tubular adenomas less than 10 mm in diameter. In this group, digital FOBT yielded positive results in 4.0% and the 6-sample test yielded positive results in 6.3%.

Table 1. **Characteristics of Included and Excluded Patients***

Variable	Included Patients (n = 2665)	Excluded Patients (n = 220)	P Value
Mean age ± SE, *y*	63.1 ± 0.14	61.7 ± 0.48	0.006
50–59 y, *n (%)*	862 (32.4)	91 (41.4)	
60–69 y, *n (%)*	1281 (48.1)	94 (42.7)	
>69 y, *n (%)*	522 (19.6)	35 (15.9)	
Male sex, *n (%)*	2579 (96.8)	214 (97.3)	>0.2
Ethnicity, *n (%)*			
White	2240 (84.2)	183 (83.1)	>0.2
Black	232 (8.7)	25 (11.4)	
Other	189 (7.1)	12 (5.5)	
Family history of colorectal cancer, *n (%)*	374 (14.0)	35 (15.9)	>0.2
Colonoscopy results, *n*			
No neoplasia	1656	135	
Tubular adenoma <10 mm	725	63	
Tubular adenoma ≥10 mm	130	13	
Villous adenoma	86	4	
High-grade dysplasia	47	2	
Cancer	21	3	
All advanced neoplasia, *n* (%)	284 (10.7)	22 (10.0)	>0.2

* Included patients had both a digital fecal occult blood test and a 6-sample test. Excluded patients were screened with only 1 type of fecal occult blood test.

Figure. **Patient selection.**



FOBT = fecal occult blood test.

The sensitivity, specificity, and likelihood of predicting significant colorectal neoplasia with FOBT are shown in **Table 3**. Results of digital FOBT and the 6-sample FOBT, respectively, were positive in 4.9% and 23.9% of all patients with advanced neoplasia (n = 284). Digital FOBT yielded positive results in only 6.4% of patients who had adenomas with high-grade dysplasia and in 9.5% of patients who had cancer. In contrast, results of the 6-sample FOBT were positive in 29.8% of patients who had adenomas with high-grade dysplasia and in 42.9% of patients who had cancer. Positive results on digital FOBT were associated with an increased likelihood of having advanced neoplasia (likelihood ratio, 1.68 [CI, 0.96 to 2.94]), but the association was not statistically significant. Negative results on digital FOBT had no predictive value (likelihood ratio, 0.98 [CI, 0.95 to 1.01]).

We analyzed the possibility that adding digital FOBT

Table 2. **Results of Digital and 6-Sample Fecal Occult Blood Tests***

Colonoscopy Findings	Overall Patients, *n*	Patients with Negative Results on Both FOBTs, *n*	Patients with Negative Results on Digital FOBT and Positive Results on the 6-Sample Test, *n*	Patients with Positive Results on Digital FOBT and Negative Results on the 6-Sample Test, *n*	Patients with Positive Results on Both FOBTs, *n*
No neoplasia					
No polypoid lesions	1218	1122	71	20	5
Nonadenomatous polyp	20	18	1	1	0
Polyp with normal characteristics on biopsy	81	73	5	3	0
Hyperplastic polyp	337	307	18	11	1
Nonadvanced neoplasia					
Tubular adenoma <10 mm	725	654	42	25	4
Advanced neoplasia					
Tubular adenoma ≥ 10 mm	130	105	19	2	4
Villous adenoma	86	61	22	3	0
High-grade dysplasia	47	33	11	0	3
Cancer	21	12	7	0	2

* FOBT = fecal occult blood test.

to a 6-sample FOBT might improve the overall sensitivity of the latter test. Only 5 patients with advanced neoplasia (1.8%) had positive results on digital FOBT and negative results on the 6-sample test. In contrast, 59 patients (20.8%) had positive results on the 6-sample test and negative results on the digital test (**Table 2**). We also considered the possibility that FOBT would be used with sigmoidoscopy. Among patients with advanced proximal neoplasia who did not have an index adenoma in the rectum or sigmoid colon (negative results on sigmoidoscopy), the 6-sample test yielded positive results in 17.2% (15 of 87 patients) and digital FOBT yielded positive results in only 4.6% (4 of 87 patients).

DISCUSSION

Screening asymptomatic persons for colorectal cancer can reduce mortality rates among those who accept the test, but only if screening is performed with adequate quality. Several large population-based studies (4–9) have shown that screening with FOBT reduces colorectal cancer mortality when positive test results are followed by colonoscopy. Each of these studies used 6-sample stool collections. Several studies have demonstrated that the 6-sample strategy (13) has a higher yield than a single FOBT. Other than our study, we know of no research evaluating both the sensitivity and specificity of the office-based digital FOBT (2).

In clinical practice, many primary care providers use a single FOBT obtained during a digital rectal examination as the primary form of screening (10, 11). This approach may be attractive because the test can be completed during the office visit and does not depend on patient adherence in returning test cards. However, little information is available about the effectiveness of digital FOBT. Two retrospective studies (12, 13) focused on the positive predictive value of digital FOBT compared with FOBT based on

Table 3. **Specificity, Sensitivity, and Likelihood Ratios for Advanced Neoplasia***

Variable	Patients	6-Sample FOBT	Digital FOBT
No advanced neoplasia, *n*†	2381		
Patients with positive FOBT results, *n*		147	70
Patients with negative FOBT results, *n*		2234	2311
Advanced neoplasia, *n*	284		
Patients with positive FOBT results, *n*		68	14
Patients with negative FOBT results, *n*		216	270
Sensitivity for advanced neoplasia, %		23.9 (19.0–28.9)	4.9 (2.4–7.4)
Specificity for advanced neoplasia, %		93.8 (92.9–94.8)	97.1 (96.4–97.7)
Positive likelihood ratio for advanced neoplasia		3.88 (2.99–5.03)	1.68 (0.96–2.94)
Negative likelihood ratio for advanced neoplasia		0.81 (0.76–0.87)	0.98 (0.95–1.01)
Positive predictive value, %		31.6 (25.4–37.8)	16.7 (8.7–24.6)
Negative predictive value, %		91.2 (90.0–92.3)	89.5 (88.4–90.7)

* Values in parentheses are 95% CIs. FOBT = fecal occult blood test.
† Patients with no advanced neoplasia included those with no neoplasia and those with tubular adenomas <10 mm.

6-sample home-based collection. In both studies, the authors hypothesized that trauma from the digital examination, use of aspirin or nonsteroidal anti-inflammatory drugs, or lack of dietary restrictions could produce false-positive results on digital FOBT and lead to unnecessary colonoscopy. Bini and colleagues (12) found similar rates of pathology in asymptomatic patients with positive results on digital FOBT or 6-sample FOBT. The second retrospective study (13), which was small, also evaluated these 2 methods in an asymptomatic sample and supported Bini and colleagues' findings. Other studies comparing digital and 6-sample FOBT collections included both symptomatic and asymptomatic patients (16–19). We know of no previous study that has evaluated the sensitivity and specificity of digital FOBT by performing colonoscopy in patients with positive and negative test results.

We compared 6-sample FOBT with digital FOBT in 2665 asymptomatic patients who were receiving subsequent screening colonoscopy, regardless of FOBT results. All colonoscopic examinations were performed by experienced endoscopists, and all studies were complete to the cecum. All patients were asymptomatic outpatients.

This study has several limitations. Our results can be generalized only to men; however, sensitivity and specificity of FOBT should not differ on the basis of sex. Second, 6-sample at-home FOBTs were developed by using rehydration. This technique may have increased the sensitivity and decreased the specificity of this test. Rehydration is not the currently recommended protocol for FOBT (2). Last, we have assumed that our experienced endoscopists identified all significant neoplasia. However, it is possible that some was missed, which would impact FOBT sensitivity (20).

In conclusion, single digital FOBT is a poor screening test for colorectal cancer and cannot be recommended as the sole test. Fewer than 5% of patients with advanced neoplasia had a positive test result. Positive results on digital FOBT performed as part of a primary care physical examination are associated with a trend toward an increased likelihood of advanced neoplasia, and colonoscopy should be performed. However, negative results do not reduce the likelihood of advanced neoplasia. If results of digital FOBT are negative, an at-home 6-sample FOBT or other screening test should be performed.

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APPENDIX

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