
Detecting Colorectal Cancer with a Large Scale Fecal Occult Blood Testing Program

DAVID I. GREGORIO, PhD, MS
PERI LOLACHI, MPH
HOLGER HANSEN, MD, DrPH

The authors are with the University of Connecticut, School of Medicine, Department of Community Medicine and Health Care.

Tearsheet requests to David I. Gregorio, PhD, MS; UCHC, School of Medicine, Dept. of Community Medicine, 263 Farmington Ave., Farmington, CT 06030; tel. (203) 679-3351.

Synopsis

The researchers analyzed outcome data for 439 persons who had positive fecal occult blood tests in

a 1984 statewide program for Connecticut residents. Among those with positive test results, colorectal cancer was diagnosed in 33 persons, 7.5 percent of the sample, during 3.5 years of follow-up. More than one-half of all cases found, 15 of 29 persons, or 52 percent, were diagnosed with in-situ or localized tumors, which are most likely to be treated successfully.

The predictive value of a positive test varied according to the screened person's age and the number of positive tests obtained from that person. Among those 60 years or older, the positive predictive value of the screening test was 9 percent, compared to 3 percent for persons younger than 60 years. Having more than one positive test was associated with a positive predictive value of 12 percent, compared to 5 percent for one positive test. The findings support the use of fecal occult blood testing for early detection of colorectal cancer.

AN ESTIMATED 158,000 NEW CASES AND 60,500 DEATHS from colorectal cancer occurred in this country during 1991, making that the second most common cause of cancer death for both sexes (1).

The disease, when detected early, is likely to be treated successfully; about 87 percent of patients diagnosed with localized colorectal cancer survive 5 years. Once metastases occur, however, the 5-year survival rate drops to 40 percent (2). Two-thirds of all those with a diagnosis of colorectal cancer presently have an advanced form of the disease.

Fecal occult blood testing of asymptomatic populations has been proposed as an effective way to detect colorectal cancer at early stages of development (3-5). Researchers of one large demonstration project found that 71 percent of the tumors detected through such efforts (12 of 17 patients) were in an early stage, compared to the more usual proportion of 31 percent of patients with localized tumors in another study of a comparable population (4). The American Cancer Society encourages annual fecal occult blood testing of all those older than 40 years (6).

Typically, 2 to 6 percent of all fecal occult blood tests of asymptomatic persons are positive (2). Because the test responds to bleeding from any gastro-intestinal source and can be positive even in

the absence of bleeding, its specificity in detecting cancer is low. Only 5 to 10 percent of positive tests are in fact positive. In a typical community-wide cancer detection project, one in which 15,000 or more tests may be completed, as many as 900 positive results may be obtained, of which between 810 and 855 may be false positive results.

The public health community needs better understanding of who is likely to participate in community-based cancer screening programs, what categories of the population are most likely to test positive, and who among those is most likely to be diagnosed with cancer. Better understanding will result in more realistic cancer control policies and better guidelines for clinicians on periodic screening for their patients.

We describe a statewide colorectal cancer screening effort involving about 16,000 residents of Connecticut in November 1984 in which 439 persons tested positive for fecal occult blood. Follow-up through the Connecticut Tumor Registry for a history of cancer of all those who tested positive was completed 3.5 years later. A total of 33 persons was diagnosed with colorectal cancer in that period. Our analysis suggests that the program achieved an effective level of early detection of colorectal cancer. The likelihood of colorectal can-

Table 1. Demographic characteristics of 462 persons with positive fecal occult blood test results and 33 of them diagnosed with colorectal cancer, Connecticut, 1984

Characteristic	Positive test (N = 462)		Confirmed by diagnosis (N = 33)	
	Number	Percent	Number	Percent
Age (in years):				
Younger than 50	77	17	0	0
50-99	80	18	5	17
60-69	171	38	14	47
70-79	99	22	8	27
80 and older	21	5	3	10
Not given	14	...	3	...
Sex:				
Men	191	52	12	41
Women	178	48	17	59
Not given	93	...	4	...
Positive tests:				
1	267	60	12	36
2	105	23	12	36
3	75	17	9	27

NOTE: Percentages are based on the total numbers of persons with known characteristics.

cer being detected among those with positive test results was found to be associated with background characteristics and prior test results.

Method

The statewide colorectal screening program was conducted through the joint sponsorship of the University of Connecticut School of Medicine and CVS, a large commercial pharmacy chain operating in Connecticut and a division of Melville Corporation, of Rye, NY. Fecal occult blood screening kits (A) were made available at no cost to the public. The program was promoted by local television stations, which broadcast information on the disease and the testing program. The kit contained three slides for specimen collection, applicator sticks, and written instructions explaining how to prepare for the test, how to obtain stool specimens, and where to return the sample.

Dietary instructions suggested that persons intending to use the test eat plenty of fresh fruits and vegetables; avoid red meat; avoid foods containing peroxidase, such as turnips and horseradish; and avoid taking aspirin-containing medications or vitamin preparations containing ascorbic acid. People were instructed to begin their diet 2 days before collecting a specimen and to continue the diet during the 3 consecutive days specimens were collected. Instructions called for two smears from different parts of each stool and a record of the date on which specimens were obtained. Specimens were to be returned promptly to a central location

using a preaddressed envelope. All slides were processed immediately upon receipt and specimens were not rehydrated prior to evaluation.

The total number of test kits distributed is not available, but about 16,000 persons submitted kits for analysis. Of those, test results suggested the presence of occult blood in the stool of 462 persons, about 2.8 to 3.0 percent. A test was considered positive if one or more slides were positive. All those having positive test results were notified of the findings by mail and encouraged to see a physician as soon as possible to determine the cause of blood in their stool. Because the screening program was conducted for casefinding, rather than as a validation study of screening efficacy, the records of the identities of those with negative results were not kept. For this reason, the test's sensitivity and specificity cannot be determined.

In April 1988, about 41 months later, the identities of 439 persons who tested positive were submitted to the Connecticut Tumor Registry to determine if they had been diagnosed with cancer. The registry is a statewide, comprehensive source on cancer incidence that has operated for more than 50 years. The registry is believed to be about 98 percent complete and is 1 of the 10 sites of the National Cancer Institute's Surveillance, Epidemiology, and End Results Program (SEER).

(The SEER Program collects information on all cases of cancer, except superficial skin cancers, that have been diagnosed since 1973 in the five States of Connecticut, Hawaii, Iowa, New Mexico, and Utah, as well as in the four metropolitan areas of San Francisco-Oakland, Detroit, Seattle-Puget Sound, and Atlanta. This population is about 10 percent of the total U.S. population. Most of the information is obtained from hospital records, including pathology and autopsy reports. SEER uses the International Classification of Diseases for Oncology (ICD-O) (7) for coding the site (topography) and morphology of all cancers.)

The remaining 23 persons with positive test results were excluded because either they resided outside Connecticut or had not provided sufficient personal information with their slides. Of the 439 persons whose names were submitted to the Connecticut Tumor Registry, 76, or 17.3 percent, were found to have been diagnosed with cancer in the 42-month interval between screening and the record search. Of these, 33 were cases of cancer of the colon or rectum (43.4 percent), and the remainder were 13 cases of breast cancer, 11 of prostate cancer, and 19 cancer of other sites. The 33 persons diagnosed with cancer of the colon or

rectum were 7.5 percent of those with positive screening tests.

Information on the age and sex of patients and the number of positive fecal occult blood tests was taken from screening project files. Data on the date of diagnosis, stage of disease, and tumor location were obtained from the Connecticut Tumor Registry. Stage of disease was recorded by the registry using a method analogous to Duke's classification. The stages were recorded as (a) carcinoma-in-situ; (b) localized disease, that which has invaded the bowel wall but has not spread beyond the serosa; (c) regional disease, that which has spread beyond the serosa but not to the lymph nodes; and (d) distant disease, that which has spread to the lymph nodes and distant sites (8).

The predictive value of test results was calculated as the proportion of colorectal cancer among persons with a positive test result.

Results

Table 1 shows the demographic characteristics of 462 persons who had positive tests during the program and 33 persons diagnosed with colorectal cancer. Based on the characteristics of those persons who had tested positive, the program was considered particularly successful in reaching the aged. Among the 448 persons who noted their age, 120 (27 percent) were older than 69 years. An additional 38 percent of persons with positive test results were ages 60 through 69 years. Among those who provided information on their sex, the numbers of men and women were roughly equal, 52 percent men and 48 percent women.

Of the 447 persons for whom there were 3 evaluable slides and a positive test result, 60 percent had 1 positive slide, 23.4 percent (105 of 447) had 2 positive slides, and 17 percent, or 1 of 6 screened, had 3 positive slides. Seventeen colorectal cancer cases (59 percent) were diagnosed among women and 12 cases (41 percent) cases were diagnosed among men. All persons diagnosed with tumors were older than 50 years, and half of them were 60 to 69 years of age. Only 9 of the 33 persons (27 percent) diagnosed tested positive for all 3 specimens. About a third of the 33 persons diagnosed had 2 positive slides and about a third tested positive on 1 slide.

Table 2 shows the tumor characteristics of the 33 persons diagnosed with colorectal cancer. Of the 33, 20 (61 percent) had tumors located in the rectum, the rectosigmoid junction, or the sigmoid colon. Stages of disease were generally favorable

Table 2. Tumor characteristics of 33 persons with positive fecal occult blood test results and diagnosed with colorectal cancer, Connecticut, 1984

Characteristic	Number	Percent
Site:		
Cecum	4	12
Ascending colon	3	9
Transverse colon	2	6
Descending colon	4	12
Sigmoid colon	9	27
Rectosigmoid colon	7	21
Rectum	4	12
Stage of disease:		
Carcinoma-in-situ	4	14
Localized	11	38
Regional	12	41
Distant	2	7
Not known	4	...
Time to diagnosis:		
Fewer than 3 months	16	57
3-9 months	8	29
More than 9 months	4	14
Not known	1	...
Diagnosis prior to 11/84	4	...

Table 3. Mean number of months from positive fecal occult blood test result to diagnosis of 33 persons with colorectal cancer, by the number of positive slides, Connecticut, 1984

Number of positive slides	Months to diagnosis ¹
1	10.0
2	4.1
3	2.7

¹F = 3.72; P = 0.04.

for treatment outcome. Excluding four persons diagnosed prior to November 1984, 52 percent, or 15 of 29, were diagnosed with in-situ, or localized, tumors. Only two, 7 percent, were diagnosed with distant metastases. Nationally, among those diagnosed with colorectal cancer, 34 percent of new cases are still localized, 38 percent exhibit regional spread, and 21 percent have evidence of distant metastases (1).

The average time from notification of positive test result to diagnosis was 5.2 months. Most patients, 16 of 28, or 57 percent, were diagnosed within 3 months of screening, and only 4 patients, 14 percent, were diagnosed after more than 9 months. For those four, the reasons for the interval between screening and diagnosis, a mean time of 19.5 months, are not known, but could have resulted from a false-positive test that was followed by the emergence of a cancer or from inadequate followup of positive test results by patients or practitioners.

Table 4. Demographic characteristics of 439 persons with positive fecal occult blood test results, including 33 persons diagnosed with colorectal cancer, with predictive values of the test, Connecticut, 1984

Characteristic	Positive test confirmed by diagnosis	Positive test	Predictive value of positive test (percent)
All subjects	33	439	7.5
Age (years): ¹			
Younger than 60	5	149	3
60 and older	25	279	9
Sex: ²			
Men	12	180	7
Women	17	171	10
Positive test slides:			
One ³	12	248	5
More than one ³	21	174	12
Intermittent ⁴	18	289	6
Consecutive ⁴	15	148	10

¹ $z = 2.13; P = 0.03.$ ² $z = 0.82; P = 0.41.$ ³ $z = 2.44; P = 0.02.$ ⁴ $z = 1.32; P = 0.19.$

Table 5. Findings of previous studies of positive test rates and positive predictive values of unhydrated hemoccult testing for colorectal cancer

Country of study and reference	Persons tested	Positives		Positives diagnosed	
		Number	Percent	Number	Percent
United Kingdom (9)	27,651	618	2.2	65	10.5
Denmark (10)	20,672	215	10.0	37	17.2
Sweden (11)	4,436	84	1.9	4	4.8

Table 3 shows the mean time from screening to diagnosis, by the number of positive screening tests. For persons with three positive slides, the average time to diagnosis was only 2.7 months. By comparison, persons with two positive slides had a mean time to diagnosis of 4.1 months. Persons with only one positive slide had an average time to diagnosis of 10 months.

Table 4 shows that the predictive value of a positive screening test was 7.5 percent. Differences in positive predictive value were noted, however, by the age of persons screened and the number of positive slides obtained. Among persons 60 years and older, the predictive value of a positive test was 9 percent, compared to 3 percent for those 60 and younger ($z = 2.13; P = 0.03$).

Statistically significant differences were not evident according to the sex of persons screened. The predictive value of a positive test was 7 percent for men and 10 percent for women ($z = 0.82; P = 0.41$).

Persons with 3 positive slides had a positive predictive value of 14 percent, those with 2 had a

predictive value of 11 percent, and those with 1 had a predictive value of 5 percent.

The difference in the positive predictive values of a positive test between persons with 1 positive slide, 5 percent, and those with more than 1, 12 percent, was statistically significant ($z = 2.44; P = 0.02$).

The positive predictive value of a test was not associated with the sequence of positive slides. Persons with 2 consecutive positive slides, 10 percent, were slightly more likely to be a true positive than those with 3, 6 percent ($z = 1.32; P = 0.19$).

Discussion

Our findings are consistent with previous studies (2-5) that noted the utility of fecal occult blood testing to identify colorectal cancer at early stages of development.

The use of communications media as part of a community-wide project was effective in screening about 16,000 persons and in detecting 33 occurrences of colorectal tumors, of which 29 were newly diagnosed. A noteworthy proportion of the tumors (52 percent) were diagnosed at an early, treatable stage of development. Moreover, a substantial portion of those (40 percent) were located beyond the reach of flexible sigmoidoscopy, and thus, were unlikely to have been detected by more invasive screening procedures.

The time from testing to diagnosis of tumors was favorable. The median time to diagnosis was 3 months, with all but four persons diagnosed within 9 months of testing. The inverse relationship between the number of positive tests and the time to diagnosis deserves further investigation.

The estimated positive test rate of 2.8 to 3.0 percent, like the positive predictive value of 7.5 percent, were consistent with recently reported screening studies (table 5). The finding that the predictive value of positive test results varied according to age of subjects and number of positive slides warrants further study, as it may aid in setting priorities for diagnostic followup.

References

1. Boring, C. C., Squires, T. S., and Tong, T.: Cancer statistics, 1991. *CA Cancer J Clin* 41: 19-51 (1991).
2. Simon, J. B.: Occult blood screening for colorectal carcinoma: a critical review. *Gastroenterology* 88: 820-837 (1985).
3. Winchester, D. P., et al.: A mass screening program for colorectal cancer using chemical testing for occult blood in the stool. *Cancer* 45: 2955-2958 (1980).
4. Cummings, K. M., et al.: Results of a public screening

program for colorectal cancer. *N Y State J Med* 86: 68-72 (1986).

5. Winawer, S. J., et al.: Progress report on controlled trial of fecal occult blood testing for the detection of colorectal neoplasia. *Cancer* 45: 2959-2964 (1980).
6. American Cancer Society: *Cancer facts and figures*, 1991. Atlanta, GA, 1991.
7. International classification of diseases for oncology. World Health Organization, Geneva, Switzerland, 1976.
8. del Regato, J. A., Spjut, H. J., and Cox, J. D., editors: *Ackerman and del Regato's cancer: diagnosis, treatment, and prognosis*. Ed. 6, C.V. Mosby, Co., St. Louis, MO, 1985, p. 548.
9. Hardcastle, J. D., et al.: Randomized, controlled trial of faecal occult blood screening for colorectal cancer: results

for the first 107,349 subjects. *Lancet* No. 8648: 1160-1164, May 27, 1989.

10. Kronborg O., et al.: Initial mass screening for colorectal cancer with fecal occult blood test: a prospective randomized study at Funen in Denmark. *Scand J Gastroenterol* 22: 677-686 (1987).
11. Kewenter, J., et al.: Screening and rescreening for colorectal cancer: a controlled trial of fecal occult blood testing in 27,700 subjects. *Cancer* 62: 645-651 (1988).

Equipment

- A. Hemoccult II test. Smith Kline Diagnostics, Inc., San Jose, CA 95134-1622.

**Attitudes of Patients
Toward Smoking
by Health Professionals**

KENNETH E. OLIVE, MD, FACP
JOHN A. BALLARD, PhD

Dr. Olive is Assistant Professor of Internal Medicine at the James H. Quillen College of Medicine at East Tennessee State University. Dr. Ballard, a social-organizational psychologist, is Visiting Assistant Professor of Business Administration at Wittenberg University, Springfield, OH.

Tearsheet requests to Kenneth E. Olive, MD, Department of Internal Medicine, East Tennessee State University, P.O. Box 70,622, Johnson City, TN 37614-0622, telephone 615-929-6282.

Synopsis

Do the smoking behaviors of physicians and nurses affect patients' perceptions of the trust and effectiveness of these health professionals? In this exploratory study, a 40-item questionnaire was

given to patients discharged from an Air Force hospital during a 4-week period. The survey resulted in 116 usable questionnaires from 40 patients who had never smoked, 44 who no longer smoked, and 32 who still smoked.

Analyses of variance in the replies to the questionnaire indicated that nonsmokers felt strongly about health professionals not modeling unhealthy behaviors, while smokers indicated they had no opinion. Regarding the relationship between the smoking habits of physicians and nurses and patients' perceptions of trust and effectiveness, smokers felt strongly there was no relationship, whereas nonsmokers indicated no opinion.

A review of the literature suggested that, on the average, health professionals who smoke may not be as effective in counseling patients to quit smoking as health professionals who do not smoke. Health professionals who smoke have the potential to affect unintentionally the smoking behaviors of others through modeling.

SOcial ACCEPTABILITY of cigarette smoking has declined in the past decade. Increasingly, smoking is seen as an addiction with serious health risks, both for the smoker and for those repeatedly exposed passively to cigarette smoke (1). Yet contemporary data indicate that 17 percent of physicians and 23 percent of nurses are cigarette smokers (2).

Given changing attitudes toward smoking and growing negative effects associated with smoking, we wondered how patients feel about cigarette

smoking by health professionals. Do patients feel physicians and nurses should set an example by avoiding unhealthy behaviors? Do the smoking behaviors of physicians and nurses affect how patients perceive the professional competence of health professionals? How does smoking affect the role of the health professional as seen by the patient? How are patients' perceptions moderated by their own smoking behavior?

Because effectiveness in communication is highly influenced by how the communicator is perceived,