The Coloscreen Self-Test for Detection of Fecal Occult Blood

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A new method for the detection of fecal occult blood was tested in a clinical setting. The test is performed by placing a chemically treated paper pad in the toilet bowl after a bowel movement and observing for color change on the pad. This method eliminates the mechanical task of handling or gathering stool by the patient. Forty-four valid trials were completed in 19 patients with known risk factors for gastrointestinal disease. A widely used reference standard (Hemoccult II) was utilized as a control method against which the study method was compared. Concordance of the results of the study method was noted in 95.8 percent of positive cases and 100 percent of negative cases. This preliminary study supports further investigation. If the aesthetic aspects of fecal occult blood testing can be improved, there may be improvements in patient compliance with screening protocols for the early detection of colorectal cancer.

The advantages and disadvantages of colorectal carcinoma detection by the finding of occult blood in stools have been recently reviewed.[1-3] Most health maintenance protocols have concurred with the American Cancer Society recommendation that three sets of two specimens be obtained annually in asymptomatic, average-risk persons 50 years of age and older.[4] The dichotomy between theory and practice remains a dilemma.[5]

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Compliance with return of three sets of guaiac-impregnated cards for early detection of occult colorectal carcinoma is frequently noted to be low (Table 1).[6-12] With increased educational efforts, compliance in a family medicine residency training program remained at less than 25 percent.[13] In this training setting, the first year of the teaching of 60-cm flexible sigmoidoscopy slightly increased compliance to 30 percent.[14] In a private practice setting, an educational program increased physician compliance with stool occult blood testing from 39 percent to 51 percent over a two-year period.[15]

In 1982 a public survey indicated an interest in the discussion of colorectal cancer as well as a willingness to do the stool blood test.[16] In an attempt to improve the aesthetic aspects of stool

Table 1. Compliance With American Cancer Society Recommendations for the Detection of Fecal Occult Blood

Study	Number of Patients	Percentage Compliance	Setting
Winchester et al[6]	54,000	26	US; media and community cancer centers
Winchester et al[7]	106,551	43	US; media and community cancer centers
Sontag et al[8]	13,522	22	US; VA hospital clinic
Hardcastle et al[9]	10,253	37	UK; a group of general practices
Leicester et al[10]	802	93	UK; symptomatic referrals to gastrointestinal clinic
Frame and Kowulich[11]	772	75	US: private family physician's office
Eggertsen and Bergman[12]	1,207	80	US; middle-class patients in a family medicine residency program

UK, United Kingdom; US, United States. The final three studies (references 10, 11, 12) represent more highly selected or motivated groups of patients.

sampling by patients, Coloscreen Self-Test, a chemically treated occult blood detecting pad, has been developed. The pad is placed into the toilet bowl and changes color to indicate a positive result. A clinical trial was designed to analyze the sensitivity and specificity of this method in patients who had high risk for pathological conditions of the intestine.

Method

Patients with a recent history of melena, guaiac-positive stool, and rectal bleeding of unknown etiology were selected for study. Patients were cared for by family medicine residents in a county hospital-based training program. Patients with coagulopathy, active hemorrhoids, hypotension, or vitamin C ingestion were excluded. Ingestion of steroidal and nonsteroidal antiinflammatory medication was quantitatively and qualitatively noted. Ingestion within the past 48 hours of aspirin, ibuprofen, or any other drug for arthritis was noted. No instructions for dietary restrictions were recommended.

No more than one set of tests for occult fecal blood was performed on any one day. The protocol was approved by the Human Subjects Protection Committee, and all patients granted informed consent prior to participation in the study. The Hemoccult II guaiac-impregnated card was used as the reference standard for the detection of fecal occult blood. These cards contain built-in quality controls for positive and negative reactions.

The study method* was a pad containing a solid guaiac-substitute reagent and a solid peroxygen compound. This pad was placed into the toilet bowl by the patient immediately following a bowel movement. Patients were instructed by a trained registered nurse in the following manner: (1) Flush the bowl twice prior to your bowel movement to minimize previously deposited residue or impurities. (2) Do not urinate into the bowl until the test is finished. (3) Do not throw toilet tissue into the bowl until the test is finished. (4) Place the pad in the toilet. (5) Observe the pad for 45 seconds. (6) Mark an X on a self-test diagram (Figure 1) to report the occurrence of a color change. (7) Perform the Hemoccult II slide procedure from stool in the bowl. (8) Perform the remainder of your toilet activity. Patients were instructed that the nurse could be paged to assist with any of the above instructions. During the data-collection phase, the nurse was not aware of the patient's clinical history or diagnostic workup.

All test pads contained built-in positive and negative quality control panels. Any trial in which all four quality-control areas were not correct was excluded from the data. All guaiac cards were interpreted on the day of collection without rehydration.[17,18]

Results

Forty-six trials were conducted on 19 patients. Average age was 57 years with a range of 40 to 72 years. Ten patients were female. All study patients completed at least one trial. Two trials were invalidated by failure of the internal quality-control sections. Quality control was evaluated by the nurse prior to flushing of the tests. These two trials were excluded from the data. The 44 remaining trials were subdivided into two groups. Positive trials were those in which the reference standard (Hemoccult II) was positive (n = 24). The study method (Coloscreen Self-Test pads) was positive in 23 of these trials. There were 20 negative reference trials. The study method was concordantly negative in all 20 trials.

Calculations for concordance of the study method with the reference method were performed. Concordance for positive tests was 95.8 percent, and concordance for negative tests was 100 percent. Although a complete diagnostic workup was not completed in two patients, 15 patients were thoroughly investigated. Eight of these investigated patients had test results that were positive for occult blood. Two patients had adenocarcinoma, two had peptic ulcer disease, two had gastritis, one had a rectal ulcer, and one was status-post gastrointestinal surgery for trauma. The only discordant (negative-positive) trial originated in one of the peptic ulcer patients. In this case there was also one concordant (positive-positive) trial on another day.

In the negative-negative subgroup of ten patients, two patients had no diagnosis determined, two patients had peptic ulcer disease, four had diverticulosis, and one had a benign polyp of the sigmoid colon. Additionally, one patient was found to have connective tissue disease. In this case the history of previous fecal blood was felt to be secondary to ingestion of large amounts of aspirin. Double-contrast barium enema and flexible sigmoidoscopy to 60 cm were negative.

Discussion

A recent state-of-the-art review on fecal occult blood testing comments on a compliance gap between motivated and unmotivated groups. Numerically this compliance is cited as 80 percent for the former and 15 percent for the latter.[17] The 22 to 43 percent range depicted in Table 1 might be viewed as data generally originating from the unmotivated group. Symptomatic Englishmen referred to a gastrointestinal specialty clinic returned guaiac slides at a rate of 92.5 percent,[10] whereas in a rural American family practice with a strong interest in screening, the overall compliance rate was 75 percent.[11] A university-based family medicine resi-

*Coloscreen Self-Test is manufactured by Helena Laboratories, PO Box 752, 1530 Lindbergh Drive, Beaumont, Texas 77707.

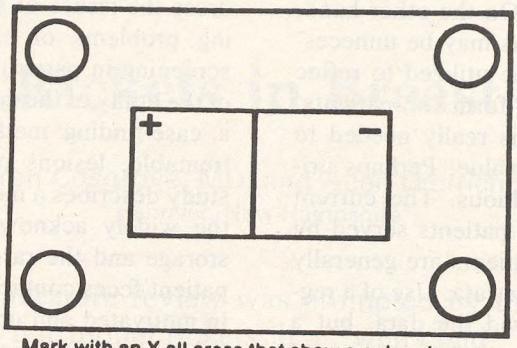

Figure 1. The Coloscreen self-test pad. Patients were given this drawing of the test pad with the instructions as printed above

dency serving a predominantly middle-class clientele reported compliance of 80 percent.[12] Regardless of physician interest and patient motivation, the handling of fecal specimens is an odious task avoided by significant numbers of motivated and unmotivated patients alike.

There are other research efforts addressing themselves to the problems of specimen storage,[18] peroxidase contamination,[19] ascorbic acid ingestion,[20] dietary restrictions,[21] and other reductionistic hypotheses.[22] Nevertheless, the clinical experience of the authors suggests that the limiting step in widespread and accurate fecal occult blood testing is the physical handling of the specimen by the patient. Many patients have reported a reluctance to lean down into a toilet bowl and attempt, with a small wooden stick, retrieval of a fresh stool specimen to be smeared on a small card, which is then stored in their house pending transport by them to their physician at some later time.

If a method of improved or equivalent accuracy could be developed and some of the described aesthetic disadvantages eliminated, trials to study the compliance of motivated and unmotivated patients would be of interest. The cost of the testing methods should be similar. At this point valid studies of the impact of this method of screening upon the natural history of colorectal cancer could proceed. The method described in this paper does eliminate the problems of handling and storage. Whether peroxidase inhibitors should be added to these pads remains a question for future research. The clinical implications of strict dietary restrictions are controversial, with several clinicians not uniformly requiring these in practice.[2,10] Furthermore, patient compliance with all of these restrictions has never been closely studied.

Limitations of this study include the small number of patients and the small amount of gastrointestinal neoplasia found within the study group. Although there is no significant difference in the positivity detection concordance between the study method (23/24) and control method (24/24), very large populations might reveal discrepancies. The immediate clinical difference would be slight. Since the targeted benefit is early detection and improved survival with colorectal carcinoma, future studies should focus on patients with polyps and carcinomas. Additionally, populations with differing disease prevalences should be studied. If concordance figures remain high, compliance comparison trials would be indicated.

Some patients admitted urinating in the bowl or placing some toilet paper in the bowl prior to testing. Although reported in fewer than three of the 44 trials, this lack of strict adherence to the test instructions may have led to specious data. All of these trials were concordant, that is, positive-

positive or negative-negative. On the other hand, the rigorous patient instructions may be unnecessary. Further studies should be utilized to refine the protocol into its simplest form for patients. Perhaps one flush is all that is really needed to achieve maximum predictive value. Perhaps urination restrictions are superfluous. The current instructions were followed by patients served by this hospital system. These patients are generally from the lower socioeconomic strata. Use of a registered nurse may have skewed the data, but a larger Hemoccult care study (utilizing trained nurse specialists) yielded a poor patient compliance rate.[23]

In summary, this study was not designed to address the issues of screening in general, eliminating problems of storage, or colorectal cancer screening in particular. It assumes an acceptance of the utility of the detection of occult fecal blood as a case-finding method for early, and therefore treatable, lesions of colorectal carcinoma. The study describes a method of testing that eliminates the widely acknowledged problem of specimen storage and the rarely acknowledged problem of patient-feces contact as an inhibitor of compliance in motivated and unmotivated groups of patients. Since this is the first clinical investigation of the Coloscreen method, this study presents no solutions. Several avenues for further investigation are suggested.

References

1. Winawer J, Fleisher M, Baldwin, et al: Current status of fecal occult blood testing in screening for colorectal cancer. CA 1982; 32:100-112
2. Rodney WM, Chun JD, Johnson RA: Colorectal cancer: Screening, treatment, and post-surgical follow-up. Semin Fam Med 1981; 2(4):267-278
3. Stroehlein JR, Newell GR: Detecting colon cancer screening: Suggestions for the primary care physician. Your Patient and Cancer, Nov, 1983, pp 87-91
4. Eddy D: Guidelines for the cancer-related checkup: Recommendations and rationale. CA 1980; 30:208-215
5. Berg AO: The periodic health examination: Expectations gone awry. J Fam Pract 1984; 19:165-166
6. Winchester DP, Schull JH, Scanlon EF, et al: A mass screening program for colorectal cancer using chemical testing for occult blood in the stool. Cancer 1980; 45:2955-2958
7. Winchester DP, Sylvester J, Maher ML: Risks and benefits of mass screening for colorectal neoplasia with the stool guaiac test. CA 1983; 33:333-343
8. Sontag SJ, Durczak C, Aranha GV, et al: Fecal occult blood screening for colorectal cancer in Veterans Administration hospital. Am J Surg 1983; 145:89-94
9. Hardcastle JD, Ferrands PA, Balfour TW, et al: Controlled trial of fecal occult blood testing in the detection of colorectal cancer. Lancet 1983; 2:1-4
10. Leicester RJ, Lightfoot A, Millar J, et al: Accuracy and value of the Hemoccult test in symptomatic patients. Br Med J 1983; 286:673-674
11. Frame PS, Kowulich BA: Stool occult blood screening for colorectal cancer. J Fam Pract 1982; 15:1071-1075
12. Eggertsen SC, Bergman JJ: A four-year experience with Hemoccult testing kits in a family medicine center. J Fam Pract 1983; 16:1021-1026
13. Rodney WM, Johnson RA, Beaber RJ, et al: Residency chart review: Preventive medicine practice as noted in the medical record. Fam Pract Res J 1982; 3:140-152
14. Rodney WM, Quan MA, Johnson RA, Beaber RJ: Impact of flexible sigmoidoscopy on physician compliance with colorectal cancer screening protocol. J Fam Pract 1982; 15:885-889
15. Frame PS, Kowulich BA, Llewellyn AM: Improving physician compliance with a health maintenance protocol. J Fam Pract 1984; 19:341-344
16. Cancer of the colon and rectum: The public perspective. CA 1983; 33:359-365
17. Winawer SJ, Fleisher M, Baldwin M, Sherlock P: Current status of fecal occult blood testing in screening for colorectal cancer. CA 1982; 32:99-112
18. Stroehlein J, Fairbanks VF, Go VLW, et al: Hemoccult stool tests: False-negative results due to storage of specimens. Mayo Clinic Proc 1976; 31:548-552
19. Caligiore P, Macrae FA, St. John DJB, et al: Peroxidase levels in food: Relevance to colorectal cancer screening. Am J Clin Nutrit 1982; 35:1487-1489
20. Jaffe RM, Kasten B, Young DJ, et al: False-negative stool occult blood tests caused by ingestion of ascorbic acid (vitamin C). Ann Intern Med 1975; 83:824-826
21. Greegor DH: Fecal occult blood test, letter. CA 1984; 34:352-353
22. Graham DT, Sackman JW, Wallis CH, Melnick JL: The Hemo-matic analyzer: A new occult blood testing device. Am J Gastroenterol 1984; 79:117-121
23. Hoffman A, Young Q, Bright-Asare P, et al: Early detection of bowel cancer at an urban public hospital: Demonstration project. CA 1983; 33:344-358