

Compliance with Fecal Occult Blood Testing: The Role of Restrictive Diets

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Abstract: In this clinical trial, 786 patients screened for colorectal cancer with fecal occult blood testing were assigned to either a "diet" or "no diet" group to examine the effect of advice to restrict intake of red meat and peroxidase-containing vegetables on patient compliance and positivity rates. Restrictive diets did not significantly decrease compliance. Interviews of patients in the "diet" group demonstrated that the majority followed instructions. Positivity rates were similar in the two groups, and clinically significant lesions were found with comparable frequency. (*Am J Public Health* 1988; 78:839-841.)

Introduction

Screening asymptomatic patients for colorectal cancer and polyps with fecal occult blood testing is recommended as part of the annual health examination.^{1,2} This practice may lead to detection of cancers at earlier stages, but mortality data from controlled trials of screening are not yet available.^{3,4} Technical aspects of testing, such as rehydration of slides,⁴⁻⁶ slide stability,⁷ number of slides performed,^{8,9} and dietary advice designed to minimize false positive reactions¹⁰⁻¹² have received attention in evaluation of screening programs because they can dramatically affect the sensitivity, specificity, and predictive value of fecal occult blood tests.

A restrictive diet intended to minimize false-positive reactions was suggested by Greeger following his observation that such advice decreased positivity rates in his practice.¹³ Diet prescription has been informally adopted as "standard test procedure" although clinical trials evaluating the effect on compliance and positivity rates in screening programs have not been performed.

Reviews of fecal occult blood testing stress problems with compliance in the general population. Compliance ranges from 15 per cent-98 per cent, with most studies in the 50 per cent-70 per cent range.¹⁴ Compliance varies with use of reminder systems,¹⁵ method of test introduction,¹⁶⁻¹⁸ and age of patients.^{10,16,17} Prescription of restrictive diets may involve considerable changes in meal planning, shopping, and food preparation, and it has been suggested that such requirements may adversely affect this critical aspect of colon cancer screening.⁶ On the other hand, diets including large quantities of red meat (containing hemoglobin or muscle peroxidase) or vegetables rich in plant peroxidases (such as broccoli, turnips, or horseradish) may increase false positive reactions, particularly if slides are rehydrated.^{6,19}

This clinical trial was designed to test the effect of restrictive diets on patient compliance. We also examined fecal occult blood test performance under different diet prescription conditions.

Methods

All patients seen in the General Medicine Clinic of the Minneapolis Veterans Administration over a six-month pe-

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riod in whom outpatient stool guaiac testing was ordered by their resident physician were included in the study (n = 786). Patients were assigned to one of the two treatment groups, "diet advice" (n = 392) or "no diet advice" (n = 394). All patients in a given week received the same diet treatment group assignment to avoid contamination of advice between groups. Assignments to treatment group alternated each week. Compliance with testing was defined by return of slides at 30 days (an interval suggested by previous survey). Noncompliant patients within each diet treatment group were subjected to either a reminder system or no reminder system, again depending on calendar period, and final compliance in patients receiving reminders was measured at 60 days.

Patients assigned to the "diet" group were given verbal and written instructions by a nurse to restrict their intake of rare meat, turnips, horseradish, aspirin, and Vitamin C for at least 48 hours prior to stool collection. They were advised to eat plenty of vegetables, fruit, popcorn, peanuts and bran in accordance with the instructions distributed by the manufacturers of Hemocult II. The "no diet" group received no diet instructions. All patients were uniformly instructed by the nurse in stool collection techniques, and asked to submit a total of six stool specimens, two from each of three days.

Patients in the "diet" treatment group who returned slides by 30 days were telephoned to assess their understanding and adherence to the restrictive diet. A standard interview was conducted to determine whether patients recalled dietary instruction and ate red meat and/or high roughage foods in preparation for stool collection. Patients were also asked the reason for the test. Patients assigned to the reminder system who did not return slides by 30 days received a letter with an additional set of guaiac cards and were contacted by phone to discuss any problems interfering with completion of the test.

Hemocult II slides were tested in the laboratory using standard procedure, without rehydration. The resident and attending physician selected diagnostic strategies to evaluate positive results.

Sample sizes were calculated for a power of 80 per cent, alpha = .05, to detect a 10 per cent difference in compliance (50 per cent-60 per cent). Treatment groups were compared using Student's t-tests.

Results

Compliance at 30 days was 80.4 per cent among patients in the "diet" group and 82.2 per cent among patients in the "no diet" group (Table 1). Compliant patients were slightly older than non-compliant patients (mean age 66.6 years vs 63.2 years).

Three hundred fifty-five patients were assigned to receive reminders if noncompliant; 66 of these patients failed to return slides by 30 days; 65 of them received reminder letters and 49 (74.2 per cent) were reached by phone. The final compliance rate in groups receiving reminders was 94.9 per cent compared to 81.2 per cent for those not receiving reminders (difference 13.7 per cent, 95% CI = 9.1, 18.3 per cent). Overall, reminders had a greater impact on compliance than assignment to dietary restriction (Figure 1).

Eighty per cent of the 315 patients advised to follow a restricted diet were contacted regarding their comprehension

TABLE 1—Test Compliance at 30 Days and Positivity Rate by Diet Group

	Restrictive Diet	No Diet	Difference	95% CI
N	392	394		
% Returned (number)	80.4 (315)	82.2 (324)	1.8	-4.0, 7.6
% Positive	5.4 (17)	6.2 (18)	0.8	-3.1, 4.7
Days required to return slides	12.5	9.7	2.8	1.82, 3.78

and adherence to dietary advice; 83.3 per cent recalled the instructions and reported attempts to modify their diet accordingly. Those advised to follow a diet for at least 48 hours prior to stool collection took, on average, 2.8 days longer to return slides to the laboratory than those not so advised (Table 1). Despite high overall compliance with testing, when asked the reason for performing stool guaiac testing, only 50 per cent of patients mentioned colon cancer, polyps, or gastrointestinal bleeding. The remainder were unable to describe a reason for the procedure.

The positivity rate in the "diet" group was 5.4 per cent, compared with 6.2 per cent in the "no diet" group (Table 1). Twenty-four of 34 guaiac-positive patients with available charts were initially evaluated with colonoscopy, or a barium enema and proctosigmoidoscopy. The results of diagnostic studies on these patients are shown in Table 2. Cancer, carcinoma in situ, villous adenomas, and adenomatous polyps were approximately evenly distributed in the "diet" and "no diet" groups.

Discussion

In this population, advice to follow a diet designed to minimize false positive reactions had only a slight and unimportant negative effect on test compliance. As in other studies, the reminder systems were extremely effective in

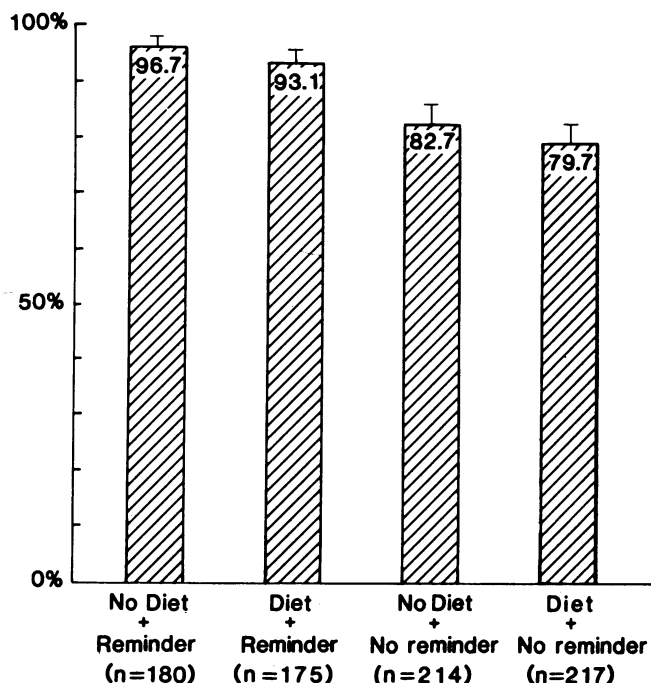


FIGURE 1—Compliance Rate at 60 Days with Fecal Occult Blood Testing among Four Study Groups (Restrictive Diet, No Diet, Reminder, No Reminder)

improving compliance.¹⁵ Even prior to reminders, compliance rates were unexpectedly high, perhaps because physicians or nurses introduced the tests, because public awareness of colon cancer screening was high, or because veterans associate compliance with continuing eligibility for free medical care. This contrasts dramatically with data from Sontag, *et al*, showing overall compliance in a veteran population of only 22 per cent,¹⁸ and compares favorably with rates seen in populations of study volunteers.^{3,4}

Other studies have shown conflicting effects of restrictive diets on patient compliance. The American Cancer Society examined various methods of test introduction and found dietary restrictions did not markedly reduce participation in a retired population (18.1 per cent vs 20.9 per cent).¹⁶ Halper and colleagues, on the other hand, reported questionnaire data suggesting noncompliant patients are more likely to view the special diet as an intrusion.¹⁰ Feifel described dropping diet prescription doubled return rates from a historic control rate of 20 per cent among 760 patients in a university clinic without an increase in positivity rates.¹²

Interview of patients advised to follow a diet supports their recollection of instructions and intent to follow them. That a significantly longer time was required to return slides in the "diet" restricted group is also indirect evidence of intent to follow restrictions. Anecdotal experience during patient interviews, however, would suggest many patients do not have a good understanding of the rationale for the diet and unintentionally violate the instructions. Approximately half the patients could not describe the reason for the screening procedure. It is surprising that we were able to achieve such a high compliance rate under these circumstances. Halper, *et al*, and Dent, *et al*, suggest compliance with fecal occult blood testing is related to health care beliefs and knowledge, specifically fear and denial of cancer,^{10,20} but other investigators have been unable to demonstrate a relationship between patient health beliefs and compliance.¹⁵

TABLE 2—Diagnoses* in 34 Guaiac-Positive Patients

Diagnosis	Restrictive Diet	No Diet
Colon Cancer (Dukes' C)	1	0
Carcinoma in situ	1	1
Villous adenoma	0	1
Adenomatous polyp	3	2
Hyperplastic polyp	0	1
Diverticulitis	5	2
Hemorrhoids	0	1
UGI sources of bleeding (gastritis)	0	1
No pathologic diagnosis**	2	3
Tests not ordered or refused	4	6
TOTAL	16	18

*The most aggressive histology or diagnosis for each patient is recorded.
**Includes diagnoses of "inflammation" or "no pathology."

Positivity rates in the "diet" and "no diet" groups were very similar: 5.4 per cent and 6.2 per cent, respectively. This is in agreement with available data,^{6,21} although all studies to date, including this one, have been conducted in select populations. A carefully designed dietary study by Macrae, *et al*, showed acceptable positivity rates on unrestricted diets using Hemoccult II slides without rehydration in young healthy subjects.⁶ Although the 0.8 per cent difference in positivity rate seen in our study is slight, even modest increases in the false positive rate may prove important in mass screening programs in determining the number of people subjected to unnecessary investigation.

The small number of positive tests evaluated in the study make it difficult to compare the positive predictive value of a test obtained following dietary advice to one obtained following no advice, but the data suggest clinically important diagnoses are made under both testing conditions. These findings do not support the practice of repeating screening if a positive test is obtained on an unrestricted diet.

In summary, this clinical trial shows restrictive diets do not markedly influence patient compliance, although they involve considerable time and effort for patients. The importance of reminder systems in achieving maximum test return rates is affirmed. Unrestricted diets do not appear to change positivity rates although larger numbers of patients would be necessary to demonstrate this conclusively.

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NCHS Data Users' Conference Scheduled for July 27-29

The National Center for Health Statistics (NCHS) will hold a data users' conference, July 27-29, at the Holiday Inn in Bethesda, Maryland. There is no registration fee for the conference, and it is open to all current and potential users of NCHS public use data files.

The conference program will include plenary sessions on policy, future directions in data collection and release, and issues related to analysis and use. Workshops will focus on the data files from specific surveys, the developments in software, and new programs in data access. The conference offers the opportunity for data users to meet with NCHS staff and with others who have used data files to exchange information, seek technical assistance, and share experiences.

For more information about the conference and to receive a registration form, write to: National Center for Health Statistics, Scientific and Technical Information Branch, 3700 East-West Highway, Room 1-57, Hyattsville, MD 20782; or call Debora Freeman at (301) 436-8500.