

Stool collection method and outcomes in immunochemical occult blood test

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ABSTRACT

BACKGROUND/AIMS: To compare the positive predictive value of an immunochemical fecal occult-blood test for colorectal neoplasms between the stool specimens obtained during the digital rectal examination and those during the routine screening.

METHODS: In a medical check-up, 1688 subjects received both an immunochemical fecal occult blood test and colonoscopy. Fecal occult-blood was tested by both of two methods; by the digital rectal examination and by the routine screening, and the positivity rate of an immunochemical fecal occult-blood test as well as the positive predictive value for colorectal cancer and large adenomatous polyp were determined in these two methods.

RESULTS: The positivity rate and the positive predictive value were 5.4% and 19.8% (4.4% for cancer and 15.4% for adenomatous polyp) in the digital rectal examination method, and 3.5% and 27.1% (6.8% for cancer and 20.3% for adenomatous polyp) in the routine screening method, respectively, indicating a significant difference in the positivity rate ($P < 0.01$) as well as the positive predictive value ($P < 0.05$) between these two methods.

CONCLUSIONS: These findings indicate that the stool specimens collected at the time of the digital rectal examination is not suitable for testing of fecal occult-blood.

Key words: Colorectal neoplasms, Digital rectal examination, Immunochemical fecal occult-blood test, Positive Predictive value

INTRODUCTION

If a screening test for cancer is to be carried out more effectively, the positive predictive value of this test for cancer should be high. In fecal occult-blood testing for colorectal cancer, fecal occult-blood is detected in stool by two stool collection methods: by testing of stool specimen obtained as part of the routine screening, or by testing of stool specimen obtained during the digital rectal examination as part of the physical examination or for screening purposes.

Appropriate evaluation of a positive result on fecal occult-blood test found at the time of the digital rectal examination is controversial, because the digital rectal examination may lead to anorectal trauma and obtaining stool samples by this means may induce to a false positive occult-blood test. Little information, however, is available regarding stool specimens obtained by the digital rectal examination method is in fact associated with a higher incidence of false positive result on fecal occult-blood test compared with those obtained by the routine screening method.

In this investigation, we performed a comparative study to evaluate the positivity rate of an immunochemical fecal occult-blood test and the positive predictive value for colorectal cancer and large colorectal adenomatous polyp between stool collected during the routine screening and those during the digital

rectal examination.

METHODS

In a medical check-up, both colonoscopy and an immunochemical fecal occult-blood test using two separate stool samples without the dietary or medicinal restriction were carried out on all participants, from June 1st, 1995, through May 31st, 1999. Fecal occult-blood was detected in stool by both of two stool collection methods, by the digital rectal examination method and by the routine screening method; and intergroup comparison was made in terms of the positivity rate of an immunochemical fecal occult-blood test as well as the positive predictive value for colorectal cancer and large colorectal adenomatous polyp.

The principles and procedures of the immunochemical slide Imdia-HemSp (a reversed passive hemagglutination test), which was used in the present investigation, are outlined as follows. The test subjects are instructed first to make a thin fecal smear on the test filter paper. Disks of the specimen from the feces-smear slides are placed in round wells in a microtiter plate. A diluent is added to extract the specimens from the disks. A portion of the extract is removed and diluted serially in the next three wells of the plate. Erythrocytes coated with anti-human-hemoglobin antibody are added to the last wells, and the mixture is incubated at room temperature for 30 minutes. Samples showing agglutination at a dilution of 1:8 are interpreted as a positive result. The absence of agglutination is interpreted as a negative. The procedures of this test are uncomplicated and the cost per slide for each test is approximately \$4.00.

Statistical analysis was performed by chi-square test, and a two-tailed *p* value of less than 0.05 was defined as statistically significant.

RESULTS

Among 1688 participants to a medical check-up for colorectal cancer, the results of an immunochemical fecal occult blood test were positive in 102 subjects (6.0%), and colorectal cancer and large colorectal adenomatous polyp (≥ 10 mm) were detected in 7 (0.4%) and 30 (1.8%) subjects by colonoscopy; the positive predictive value for colorectal cancer and large colorectal adenomatous polyp were 4.9% and 20.6% for those who were positive results on an immunochemical fecal occult blood test (Table 1).

The positive cases of an immunochemical fecal occult blood test were 91 for the digital rectal examination method and 59 for the routine screening method. Thus, the positivity rate of an immunochemical fecal occult-blood test in these two groups was 5.4% and 3.5%, respectively, indicating a substantial significant difference between the two methods ($p < 0.01$). Colorectal cancer and large colorectal adenomatous polyp were detected in 4 and 14 in the digital rectal examination method and 4 and 12 in the routine screening method, respectively. The positive predictive value for colorectal cancer and large colorectal adenomatous polyp were 19.8% (4.4% for cancer and 15.4% for adenomatous polyp) in the digital rectal examination method, and 27.1% (6.8% for cancer and 20.3% for

adenomatous polyp) in the routine screening method, respectively, and there was a substantial significant difference between these two methods ($p < 0.05$) (Table 2).

DISCUSSION

In the present study, the positivity rate and the positive predictive value were 5.4% and 19.8% in the digital rectal examination method and 3.5% and 27.1% in the routine screening method. These findings suggest that anorectal local trauma induced by the gloved finger during digital rectal examination can be considered a cause of the lower positive predictive value, and indicate that the stool samples collected at the time of digital rectal examination method is inadequate for testing of fecal occult-blood.

A comparative study showed that the stool specimen obtained during the digital rectal examination was unsuitable for the testing of fecal occult-blood, because the positive predictive value for colonic neoplasms of fecal occult-blood testing of stool sample obtained during the digital rectal examination was lower than that of testing of stool sample obtained by the patients with routine screening.¹ Longstreth has also editorialized that to perform fecal occult blood testing on stool obtained at the time of digital rectal examination was "a procedure of little value" and was to be discouraged.² The findings in the present investigation substantiate the view in these previous studies on the lower predictive value of stool samples obtained during the rectal examination.

Conversely, some investigations demonstrated that the patients with positive results on fecal occult-blood test through the digital rectal examination had as many as colonic disorders as the patients identified through the routine screening.^{3, 4} In addition, a prospective study found that the patients with positive fecal occult-blood test, which stool specimens were obtained as part of the routine screening or stool specimens obtained during the digital rectal examination, upper gastrointestinal lesions were identified more frequently than colonic lesions.⁵

Even if there is no bleeding from colorectal cancer or adenomatous polyp, another gastrointestinal pathology such as, upper digestive tract diseases, diverticulosis, hemorrhoids, and angiodysplasia may lead to positive results on fecal occult-blood test due to the characteristics of fecal occult-blood test that aims to detect blood in stool. In a separate article,⁶ we demonstrated that an immunochemical fecal occult-blood test was inadequate as a screening test for stomach cancer and that further examination of upper digestive tract was unnecessary in cases where fecal occult-blood was positive but there was no evidence of diseases in colon and rectum.

Theoretically, this view is based on the concept that hemoglobin derived from upper digestive tract is degenerated in gastrointestinal tract by pepsin and pancreatic and intestinal proteases, and is thus not detected by immunochemical fecal occult-blood testing.⁷ So far, however, there have been different reports that upper gastrointestinal pathology influenced the results of guaiac-impregnated

occult-blood test.⁸⁻¹³ The difference may be explained by the fact that we used an immunochemical test in that investigation.

Diverticulosis, hemorrhoids, and angiodysplasia may also lead to positive results on fecal occult-blood test. Although some studies by a chemical occult-blood test suggest that they are not thought to be a cause of positive occult-blood stool and a positive result of occult-blood should be considered to deserve a complete evaluation regardless the presence of these disorders,^{14, 15} the association between these disorders and the results of immunochemical fecal occult-blood test has not been completely investigated. In order to assess the influence of above gastrointestinal diseases to the results of immunochemical occult-blood test, it is desirable to determine the diagnostic validity of this test for these diseases under the desirable method.^{16, 17}

One of the reasons why it may be inappropriate and misleading to perform guaiac-impregnated fecal occult-blood testing on stool obtained by digital rectal examination is that the subjects probably have not followed the specific dietary and medicinal avoidance guidelines recommended before collecting stool samples for occult blood testing.^{7, 18, 19} A major advantage of immunochemical fecal occult-blood tests, which use antibodies directed against human hemoglobin epitopes, is no dietary and medicinal restrictions. Accordingly, no restrictions of diet or drug can not be considered to be a cause of high positivity rate as well as lower predictive value on stools obtained by the digital rectal examination.

In conclusion, our results indicate that the positive predictive value of fecal occult-blood testing of stool collected at the time of digital rectal examination is inferior than that of testing of stool collected during the routine screening, and that the stool specimens obtained during the digital rectal examination should not be tested for fecal occult-blood.

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Table 1 Results of both an immunochemical fecal occult blood testing and colonoscopy in a medical check-up

I. No. of examinees	1688
II. No. of positive occult-blood cases (II / I)	102 (6.0%)
III. No. of detected colorectal neoplasms by colonoscopy (III / I)	37 (2.2%)
Cancer	7 (0.4%)
Adenomatous polyp ($\geq 10\text{mm}$)	30 (1.8%)
IV. No. of detected colorectal neoplasms by occult-blood (IV / I)	26 (1.5%)
Cancer	5 (0.3%)
Adenomatous polyp ($\geq 10\text{mm}$)	21 (1.2%)
V. Positive predictive value of occult-blood test (IV II)	
for colorectal neoplasms	25.5%
for cancer	4.9%
for adenomatous polyp ($\geq 10\text{mm}$)	20.6%

Table 2 Comparison of positivity rate and positive predictive value between stool collected by digital rectal examination method and those collected by routine screening method.

	Stool collection methods	
	Digital rectal examination	Routine screening
I. No. of total cases	1688	1688
II. No. of positive occult-blood cases	91	59
III. Positivity rate	5.4*	3.5
IV. No. of detected colorectal neoplasms	18 (1.1%)	16 (0.9%)
Cancer	4 (0.2%)	4 (0.2%)
Adenomatous polyp ($\geq 10\text{mm}$)	14 (0.8%)	12 (0.7%)
V. Positive predictive value of occult-blood test		
for colorectal neoplasms	19.8%**	27.1%
for cancer	4.4%	6.8%
for adenomatous polyp ($\geq 10\text{mm}$)	15.4%	20.3%

* $P < 0.01$ for difference in positivity rate of fecal occult-blood test between routine screening and digital rectal examination methods.

** $P < 0.05$ for difference in positive predictive value of fecal occult-blood test for colorectal neoplasms between routine screening and digital rectal examination methods.