

Specificity of fecal occult blood test  
on stool collected by digital rectal examination

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## ABSTRACT

**BACKGROUND/AIMS:** To compare the diagnostic accuracy of an immunochemical fecal occult-blood test for colorectal cancer between the stool specimens obtained during the routine screening and those during the digital rectal examination.

**METHODOLOGY:** One hundred and fourteen patients with colorectal cancer and 228 healthy controls served as subjects of the study. Fecal occult-blood was tested by both of two methods; by the routine screening and by the digital rectal examination, and the sensitivity and specificity of an immunochemical fecal occult-blood test were determined in these two methods.

**RESULTS:** The sensitivity and specificity were 79.8% and 96.5% in the routine screening method, and 86.0% and 79.8% in the digital rectal examination method, respectively, showing a significant difference in the specificity ( $P < 0.01$ ) between these two stool collection methods. There was no significant difference in the sensitivity between these two stool collection 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 cancer, Diagnostic Accuracy, Digital rectal examination, Immunochemical fecal occult-blood test.

## INTRODUCTION

The sensitivity and specificity should be high when a screening test for cancer is to be performed effectively. 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, and test sensitivity and specificity may be affected by the method of stool collection.

The diagnostic yield of a positive result on fecal occult-blood test found at the time of the digital rectal examination is disputed, 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 that 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 case control study to compare the diagnostic accuracy of an immunochemical fecal occult-blood test between stool samples collected during the routine screening and those during the digital rectal examination, from the results obtained with colorectal cancer patients and healthy controls.

## MATERIALS AND METHODS

One hundred and fourteen patients with colorectal cancer, including 46 cases of Duke's stage A cancer, 44 cases of Duke's stage B cancer, 22 cases of Duke's stage C cancer and 2 cases of Duke's stage D cancer, diagnosed by colonoscopy with biopsy and classified after operation, and 228 healthy controls found to be normal through upper as well as lower tracts endoscopy, a total of 342 people, served as subjects of this investigation.

An immunochemical fecal occult-blood test using four separate stool samples without the dietary or medicinal restriction was carried out on all subjects, from August 1st, 1995, through July 31st, 1998, by both of two stool collection methods; by the routine screening method and by the digital rectal examination method, and intergroup comparison was made in terms of the diagnostic accuracy of an immunochemical fecal occult-blood test for colorectal cancer.

The principles and procedures of the immunologic slide Iatro Hemcheck (a latex agglutination inhibition test), which was used in the present study, are outlined as follows. A small plastic tube containing buffer, sealed by a cap with a collection stick is prepared for the collection of feces. Firstly, those being examined are asked to stick the tip of collection stick into the fecal sample several times, then to seal the cap. One drop of the fecal liquid in the plastic tube are put in well and mixed with anti-human-hemoglobin antibody attached to latex particles. Samples are classified as positive results when no agglutination occurred within 1.5 minutes after test procedure was completed and negative results when agglutination occurred. This test does not cause the prozone phenomenon and the procedures of this test are uncomplicated and the cost per slide for each test is approximately \$4.00.

Chi-square test was used as need to determine statistical significance, and the level of significance was regarded at a risk of 5% or below.

## RESULTS

Table 1 shows the results of an immunochemical fecal occult-blood test using four separate stool samples on 114 patients with colorectal cancer and 228 healthy controls. Positive cases among patients with colorectal cancer and healthy subjects were found to be 91 and 8 for the routine screening method, 98 and 46 for the digital rectal examination method, respectively. Accordingly, the sensitivities and specificities of an immunochemical fecal occult-blood test were calculated as 79.8% and 96.5% for the routine screening method, 86.0% and 79.8% for the digital rectal examination method, respectively, showing a significant difference in the specificity between these two stool collection methods ( $p < 0.01$ ) (Table 2). There was no significant difference in the sensitivity between these two methods.

## DISCUSSION

Three randomised controlled studies of fecal occult-blood screening for colorectal cancer using patient-collected stool have been shown to be associated with reducing mortality from colorectal cancer (1-3). Some physicians perform fecal occult-blood test on stool obtained during the digital rectal examination, however, the clinical impact of this practice is controversial. For this reason, we have evaluated the diagnostic accuracy of this test, by the results obtained with colorectal cancer patients and healthy subjects.

In the present study, the sensitivities and specificities were 79.8% and 96.5% in the routine screening method and 86.0% and 79.8% in the digital rectal examination 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 specificity, and indicate that the stool samples collected at the time of digital rectal examination is not suitable for testing of fecal occult-blood. Marks et al. demonstrated that the stool collected during the digital rectal examination was not adequate for the testing of fecal occult-blood, because the positive predictive value of this test for colonic neoplasms of stool obtained at the time of digital rectal examination was lower than that of testing of stool sample obtained by the patients with routine screening (4). Longstreth has also editorialized that to perform fecal occult blood testing on stool obtained during the digital rectal examination was "a procedure of little value" and was not to be discouraged (5). 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.

In contrast, some investigations demonstrated that the patients with positive results on fecal occult-blood test through the digital rectal examination had as many colonic disorders as the patients identified through the routine screening (6,7).

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 (8).

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 (9,10,11). 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 in the present investigation can not lead to a cause of higher positivity rate as well as lower predictive value on stools obtained by the digital rectal examination.

Although a hospital based case control study to investigate both the cancer cases and the healthy controls employed here gives us information about the accuracy of screening test, a prospective study after screening on asymptomatic people is more desirable to evaluate the diagnostic accuracy of fecal occult blood as a screening test for colorectal cancer because a retrospective study aims the patients with cancer in clinical stage. To confirm the findings of the present investigation, it would be necessary to conduct a population based follow-up study.

In conclusion, our results indicate that the diagnostic accuracy 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 an immunochemical fecal occult blood testing on 114 patients with colorectal cancer and 228 healthy subjects by two stool collection methods

	Stool collection methods					
	Routine screening			Digital rectal examination		
	Positive	Negative	Total	Positive	Negative	Total
Colorectal cancer	91	23	114	98	16	114
Healthy subjects	8	220	228	46	182	228

Table 2 Comparison of sensitivity and specificity of an immunochemical fecal occult-blood testing between routine screening and digital rectal examination methods.

	Stool collection methods	
	Routine screening	Digital rectal examination
Sensitivity (%)	79.8	86.0
Specificity (%)	96.5*	79.8

\*P<0.01 for difference in specificity of an immunochemical fecal occult-blood test between routine screening and digital rectal examination methods.