

## Relationship between Irritable Bowel Syndrome and Results of Immunochemical Fecal Occult Blood Test

Hidenori Nakama, M.D., Ph.D.

Correspondence to

H. Nakama

Matsumoto University

Ni-imura 2095-1, Matsumoto, 390-8621 Japan

TEL: +81-263-48-7293 FAX: +81-263-48-7290

E-mail: nakama@matsu.ac.jp

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## ABSTRACT

*Objectives:* This study was conducted to investigate the influence of irritable bowel syndrome to the results of fecal occult blood test.

*Methods:* In a hospital-based case-control study, occult blood test with a 2-days method was performed on the patients with irritable bowel syndrome and the healthy subjects to evaluate the positivity rate of occult blood test. In a screening-program-based cross sectional study, the subjects who underwent occult blood screening with a 2-day method were divided into two groups, according to the results of questionnaire on irritable bowel syndrome, and the positivity rate of occult blood test as well as the predictive value for colorectal cancer were determined in these two groups.

*Results:* Among 206 cases including 103 irritable bowel syndrome and 103 healthy subjects, the test was positive in 9 irritable bowel syndrome and 6 healthy subjects. The positivity rate to irritable bowel syndrome and healthy subjects was calculated to be 8.7% and 5.8%, respectively. There was no significant difference in the positivity rate between these two groups. Among 24157 subjects, who underwent occult blood screening, 1348 subjects were positive to irritable bowel syndrome, and 22809 subjects were negative. The positivity rate of occult blood test was 6.8% for irritable bowel syndrome and 6.2% for non-irritable bowel syndrome, and the predictive value for colorectal cancer was 3.3 and 3.0, indicating no substantial difference between these two groups.

*Conclusions:* These results suggest that irritable bowel syndrome has

no influence to the results of fecal occult blood test.

**Key words:** Diagnostic Validity, Immunochemical Fecal Occult Blood Test, Irritable Bowel Syndrome

## INTRODUCTION

Colorectal cancer screening by fecal occult blood has been confirmed through three randomised controlled studies [1-3] to be effective for reducing mortality. This implies that the fecal occult blood test has been evaluated as an effective test for colorectal neoplasms. As is shown by the use of Hemoccult II in the above randomised controlled trials, the primary test for colorectal cancer screening adopted in Western countries has been the guaiac-impregnated chemical testing.

The immunochemical fecal occult blood test is now almost established as a screening method for colorectal cancer in Japan [4-8]. I have previously reported on the high diagnostic accuracy of this test, compared with the conventional chemical test such as Hemoccult II, based on the results of diagnosis with this test in colorectal cancer patients and healthy controls as well as the results of mass screening for colorectal cancer using this test [9]. However, the positive predictive value of immunochemical fecal occult blood test for colorectal neoplasia is not so high.

Irritable bowel syndrome is common in general practice, and may lead to a positive result on the immunochemical fecal occult blood test due to the characteristics of this test with high sensitivity. Nevertheless, little information is available on the relationship between irritable bowel syndrome and the results of fecal occult blood test. In this study, I investigated the diagnostic accuracy of the immunochemical fecal occult blood test for irritable bowel syndrome

and evaluated the influence of this disorders to the results of the immunochemical fecal occult blood test.

## METHODS

### A. Hospital-based case-control study

The study was performed on 103 patients with irritable bowel syndrome diagnosed by the physicians and 103 healthy subjects, with no abnormal sign from endoscopy of upper and lower digestive tracts. To these subjects, an immunochemical fecal occult blood test with a 2-day method was carried out to evaluate the diagnostic value for irritable bowel syndrome.

### B. Screening-program-based cross-sectional study

The screening program for colorectal cancer using an immunochemical fecal occult blood test was performed on 24157 residents within Nagano Prefecture. The subjects were over age of 40. Each of these screening subjects received an immunological fecal occult blood test using a 2-day method without dietary restriction. Any cases found to be positive were examined either by total colonoscopy or, in 5% of cases, by double-contrast barium enema.

All subjects who underwent examinations were divided into two groups, according to the results of a self-completed questionnaire regarding the presence of diagnosed irritable bowel syndrome; and intergroup comparison was made in terms of their positivity rate of fecal occult blood test as well as predictive value for colorectal cancer.

The principles and procedures of the immunological slide Imdia-Hem Sp (a reversed passive hemagglutination test), which was used in this study, are outlined as follows. First, the test subjects are instructed 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 deluted 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 test procedures of this commercial test are not complicated and are performed in a hospital laboratory or in a physician's office. Also, it does not require a specially trained individual to perform and evaluate the test results. The manufacturer's price per slide for each test is approximately \$2.80.

Statistical analysis was performed by McNemar's test and a P value of less than 0.05 was defined as statistically significant.

## RESULTS

### A. Hospital-based case-control study

Table 1 summarizes the results of fecal occult blood test in the patients with irritable bowel syndrome and healthy subjects. The results of fecal occult blood test were positive in 9 subjects with

irritable bowel syndrome and 6 healthy subjects. Therefore, the positivity rate of fecal occult blood test to irritable bowel syndrome and healthy subjects was 8.7% and 5.8%, respectively. There was no significant difference in the positivity rate between the patients with irritable bowel syndrome and the healthy subjects.

#### B. Screening-program-based cross-sectional study

Among 24157 subjects who underwent the examination for colorectal cancer, the results of the fecal occult blood test were positive in 1503 subjects(6.2%), among whom colorectal cancer was detected in 46 subjects(0.2%), and the positive predictive value for colorectal cancer was 3.1 to those who showed the positive to fecal occult blood test and 3.5 to those who received the further examination(Table 2).

In 1348 subjects of irritable bowel syndrome group and in 22809 subjects of non-irritable bowel syndrome group, positive cases of fecal occult blood test was 91 for irritable bowel syndrome group and 1412 for non-irritable bowel syndrome group. Thus, the positivity rate of fecal occult blood test in these groups was 6.8% and 6.2%, respectively, and there was no substantial difference between the two groups. Also, colorectal cancer was detected in 3 and 43 subjects in these two groups, respectively. The predictive value for colorectal cancer was 3.3 for irritable bowel syndrome group and 3.0 for non-irritable bowel syndrome group, and there was no substantial difference between these two groups (Table 3).

## DISCUSSION

The screening examination for colorectal cancer using the immunochemical fecal occult blood test is widely propagated in Japan, while this test aims to detect the blood in feces [10], another digestive tract diseases such as stomach cancer, peptic ulcer, hemorrhoid, colitis and anal diseases may lead to a positive result on the fecal occult blood test. Nevertheless, the problem of diagnostic accuracy of the immunochemical fecal occult blood for these disorders has not yet been completely investigated.

In Japan, the screening programs for colorectal cancer are often performed with a self-completed questionnaire on the diagnosis of irritable bowel syndrome. For this reason, I attempted to investigate the influence of irritable bowel syndrome as functional colitis to the results of the immunochemical fecal occult blood test.

Various types of study design can be used to assess the relation between the diagnostic tests and the disease. In this study, I used two approaches to evaluate the diagnostic accuracy of fecal occult blood test for irritable bowel syndrome: the hospital-based retrospective approach to study the affected cases and the healthy subjects, and the screening-program-based approach to calculate the positivity rate as well as the predictive value for colorectal cancer. In the hospital-based retrospective study, there was no significant difference in the positivity rate of fecal occult blood test between irritable bowel syndrome and healthy subjects. Also, in the



screening-program based cross sectional study, there was no substantial difference in the positivity rate of fecal occult blood test as well as the predictive value for colorectal cancer between irritable bowel syndrome group and non-irritable bowel syndrome group. These data show that irritable bowel syndrome has no influence to the results of fecal occult blood test.

Although irritable bowel syndrome in the population screening were based on a self-reported questionnaire, the diagnosis has not been made by the subjects themselves, but by the physicians. Accordingly, the results of this study are likely to have the reliability about the diagnosis of this disorder. However, special attention should be paid to the bias in this study resulting from use of a self-completed questionnaire.

In conclusion, despite the limitation of this study, our results suggest that irritable bowel syndrome has no influence to the results of the immunochemical fecal occult blood testing.

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Table 1 Results of immunochemical fecal occult blood test on patients with irritable bowel syndrome and healthy subjects

	Fecal occult blood test			Positivity rate (%)
	+	-	Total	
Irritable bowel syndrome group	9	94	103	8.7
Healthy subjects group	6	97	103	5.8

Table 2 Results of Immunochemical fecal occult screening for colorectal cancer

I. No. of screenees	24157
II. No. of positive occult blood cases (II / I)	1503 ( 6.2%)
III. No. of examinees (III / II)	1321 (87.9%)
IV. No. of detected cancer cases (IV / I)	46 ( 0.2%)
V. Positive predictive value	
for positive occult blood cases:IV / II	3.1
for examinees:IV / III	3.5

Table 3 Comparisons of positive occult blood cases and predictive value for colorectal cancer between irritable bowel syndrome and non-irritable bowel syndrome groups in colorectal cancer screening

	Irritable bowel syndrome group	Non-irritable bowel syndrome group
I. No. of total cases	1348	22809
II. No. of positive occult blood cases	91	1412
III. Positivity rate(%)	6.8	6.2
IV. No. of examinees	81	1240
V. No. of colorectal cancer cases	3	43
VI. Positive predictive value		
for positive occult blood cases: V/II	3.3	3.0
for examinees: V/IV	3.7	3.5