Clinical Diagnostic Accuracy of Faecal Occult Blood Test for Anal Diseases

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Purpose: To investigate the diagnostic accuracy of faecal occult blood test (FOBT) for anal diseases and to evaluate the relationship of this disorder to the results of FOBT.

Methods: In a hospital-based retrospective study, FOBT using faecal samples collected on two consecutive days was performed on patients with anal disease, such as internal as well as external haemorrhoids and anal fissure, patients with colorectal cancer and healthy subjects to evaluate the diagnostic accuracy of FOBT. In a screening-programme-based cross-sectional study, the subjects who underwent colorectal cancer screening by FOBT using the 2-day method were divided into two groups according to the results of a questionnaire on anal diseases; the positive rate of FOBT as well as the predictive value for colorectal cancer were determined in the two groups.

Results: Among 300 cases, including 100 anal diseases, 100 colorectal cancers and 100 healthy subjects, the test was positive in 12 anal diseases, 82 colorectal cancers and six healthy subjects. The sensitivity to anal diseases and colorectal cancer was calculated to be 12% and 82%, respectively, and the specificity was 95%. A significant difference was noted in the sensitivity between anal diseases and colorectal cancer (P < 0.001). Among 21 724 subjects, who underwent colorectal cancer screening by FOBT using the 2-day method, 2395 subjects were positive for anal diseases, and 19 329 subjects were negative. The positive rate of FOBT was 13.6% for the anal diseases group and 6.8% for the non-anal diseases group, and the predictive value for colorectal cancer was 2.9% and 3.0%, indicating no substantial difference between the two groups.

Conclusions: These results reveal that FOBT is inferior for the diagnosis of anal diseases, and anal diseases have little relationship to the results of FOBT.

Key words: Diagnostic accuracy, FOBT, anal diseases.

INTRODUCTION

The immunochemical FOBT is now almost established as a screening method for colorectal cancer in Japan [1]. We have previously reported on the high diagnostic accuracy of this test compared with conventional chemical tests, 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 [2].

However, internal as well as external haemorrhoids and anal fissure may lead to a positive result on FOBT because of the characteristics of this test, it is desirable to determine the diagnostic accuracy of FOBT for these diseases. Nevertheless, little information is available on the relationship between anal diseases and the results of FOBT. In this study, we investigated the diagnostic accuracy of FOBT for the above anal diseases and evaluated the relationship of these disorders to the results of FOBT.

MATERIALS AND METHODS

Hospital-based retrospective study

The study was performed on 300 cases, including 100 cases of anal diseases with diagnosis established by endoscopy of the lower digestive tract, such as 48 internal haemorrhoid cases, 43 external haemorrhoid cases, and nine anal fissure cases, 100 cases of colorectal cancer with diagnosis established by endoscopy of the lower digestive tract and biopsy, and 100 cases of healthy subjects with no abnormal signs from endoscopy of the upper and lower digestive tract. For these subjects, FOBT, using faecal samples collected on two consecutive days, was carried out to evaluate the sensitivity and the specificity for anal diseases and colorectal cancer.

Screening-programme-based cross-sectional study

The screening programme for colorectal cancer using FOBT was performed on 21 724 residents within Nagano Prefecture. The subjects were over the age of 40 and principally asymptomatic. Each of these mass screening subjects received an immunological FOBT 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 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 anal diseases; intergroup comparison was made in terms of their positive rate of FOBT as well as a predictive value for colorectal cancer.

The principles and procedures of the immunological slide Monohaem (Nihon Pharmaceutical, Japan), which was used in the present study, are as follows. First, those being screened are asked to make a thin faecal smear on the test filter paper. If human haemoglobin is present in the faecal sample, it will participate in an antigen–antibody reaction with the monoclonal antibody in the filter paper. The reacted sample is then washed to remove components other than haemoglobin, and a colour coupler is added. Oxygen is dissociated from hydrogen peroxide by the peroxidase-like activity of human haemoglobin, which oxidizes tetramethyl-benzidine, leading to the appearance of a green colour. The presence of human haemoglobin is thus indicated by the appearance of this green coloration. The procedures of this test are uncomplicated, and the cost per slide for each test is approximately 300 yen.

A statistical analysis was performed using a Chi-square test, and a \( P < 0.05 \) was defined as being statistically significant.

RESULTS

Hospital-based retrospective study

Table 1 summarizes the results of FOBT in the cases of anal disease, colorectal cancer and healthy subjects. The results of FOBT were positive in 12 subjects with anal diseases (six with internal haemorrhoid, five with external haemorrhoid and one with anal fissure), 82 subjects with colorectal cancer and five healthy subjects. Therefore, the sensitivity of FOBT to anal diseases and colorectal cancer was 12.0% and 82.0%, respectively, and the specificity was 95.0%. Significant difference was noted in the sensitivity between anal diseases and colorectal cancer.

**TABLE 1. Results of faecal occult blood tests on patients with anal disease, patients with colorectal cancer and normal subjects**

<table>
<thead>
<tr>
<th>Faecal occult blood test</th>
<th>Diagnostic accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
</tr>
<tr>
<td><strong>Anal diseases</strong></td>
<td>12*</td>
</tr>
<tr>
<td><strong>Colorectal cancer</strong></td>
<td>82</td>
</tr>
<tr>
<td><strong>Normal subjects</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>99</td>
</tr>
</tbody>
</table>

\*\( P < 0.001 \) for difference between anal diseases and colorectal cancer.

A statistical analysis was performed using a Chi-square test, and a \( P < 0.05 \) was defined as being statistically significant.

**TABLE 2. Results of mass screening program for colorectal cancer**

| I | Number of patients screened | 21724 |
| II | Number of positive occult blood cases (II/I) | 1496 (6.9) |
| III | Number of examinees (III/II) | 1335 (89.2) |
| IV | Number of detected cancer cases (IV/I) | 45 (0.2) |
| V | Positive predictive value | — |
| V | for positive occult blood cases: IV/II | 3.0 |
| V | for examinees: IV/III | 3.4 |

\( (P < 0.001) \), whereas there was no difference in the sensitivity among internal haemorrhoid, external haemorrhoid and anal fissure.

**Screening-programme-based cross-sectional study**

Among 21724 subjects who underwent an examination for colorectal cancer, the results of FOBT were positive in 1496 subjects (6.9%), among whom colorectal cancer was detected in 45 subjects (0.2%); the positive predictive value for colorectal cancer was 3.4 for those who were positive on the FOBT and 3.0 for those who received either colonoscopy or barium enema (Table 2).

In 2395 subjects of the anal diseases group and in 19329 subjects of the non-anal diseases group, positive cases of FOBT were 172 for the anal diseases group and 1324 for the non-anal diseases group. Thus, the positive rate of FOBT in these groups was 7.2% and 6.8%, respectively, and there was no substantial difference between the two groups (Table 3). Also, colorectal cancer was detected in five and 40 subjects in the two groups, respectively. The predictive value for colorectal cancer was 2.9 for the anal diseases group and 3.0 for the non-anal diseases group, and there was no substantial difference between the two groups (Table 3).

**DISCUSSION**

The screening examination for colorectal cancer using FOBT is widely propagated in Japan [3]. Whereas this test aims to detect blood in the faeces [4], anal diseases such as internal as well as external haemorrhoids and...
anal fissure may also lead to a positive result on FOBT. Nevertheless, the problem of diagnostic accuracy of FOBT for anal diseases has not yet been completely investigated.

In Japan, the prevalence of haemorrhoids is high, and screening programmes for colorectal cancer are often performed with a self-completed questionnaire on the diagnosis of anal diseases. Furthermore, a recent report from England suggests the high prevalence of rectal bleeding [5]. Given this background, we attempted to investigate the diagnostic accuracy of FOBT for anal diseases and to evaluate whether or not the colorectum should be examined when the FOBT is positive and there are also signs of anal disease.

In the present study, we used two approaches to evaluate the diagnostic accuracy of FOBT for anal diseases: a hospital-based retrospective approach to study the affected cases and the healthy subjects, and a screening-programme-based approach to calculate the positive rate as well as the predictive value for colorectal cancer. In the hospital-based retrospective study, there was a significant difference in the sensitivity of FOBT between anal diseases and colorectal cancer. In the screening-programme-based cross-sectional study, on the other hand, there was no substantial difference in the positive rate of FOBT as well as the predictive value for colorectal cancer between the anal diseases group and the non-anal diseases group. These data show that FOBT is inferior for the diagnosis of anal diseases, and that examination of the colorectum is necessary in cases where the FOBT is positive and there is also evidence of anorectal diseases such as haemorrhoids and anal fissure.

Even if bleeding from anal diseases exists, theoretically two factors may lead to a negative result on the FOBT; these are intermittent bleeding from the diseases and faecal sampling from an inappropriate site. It has been shown that intermittent bleeding is the possible cause of a negative FOBT result in the study of colorectal polyps [6,7]. As to the inappropriate site of stool sampling, it has been suggested that, particularly in rectal cancers, blood can adhere to part of the faeces [8,9]. Therefore, depending on the characteristics of bleeding or the site of stool sampling, different mechanisms may yield a negative result.

Although the data on internal as well as external haemorrhoids and anal fissures in the population screening were based on a self-reported questionnaire, the diagnoses of these anal diseases were not made by the subjects themselves, but by the physicians. Accordingly, the results of this study are likely to have a good reliability with regard to the diagnosis of these disorders. However, special attention should be paid to the bias in this study resulting from use of self-completed questionnaire.

In order to evaluate the diagnostic accuracy of screening a variety of study designs can be used. Although the present study gives us information about the validity of FOBT for anal diseases, the most desirable method would be to carry out both a screening test and further examination of all asymptomatic people. To confirm the findings of this study, it would be necessary to conduct both FOBT and colonoscopy on all asymptomatic subjects.

In conclusion, our results suggest that internal as well as external haemorrhoids and anal fissure have little relationship to the results of FOBT, and the positive results of FOBT deserve a further examination, regardless of the presence of anal diseases.

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