

Quantitative Analysis of Fecal Hemoglobin Concentration in Colorectal Cancer Patients – The Values in the Screening and Diagnosis of Colorectal Cancer

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Abstract: Objective: To use immunochemical detection of fecal hemoglobin amount as a technical method, to perform a fecal immunochemical test (FIT) on the fecal specimens of research subjects who were going to undergo colonoscopy. The recorded results are compared and analyzed, and the sensitivity and specificity of the detection method in the diagnosis of colorectal cancer were evaluated. **Methods:** Three hundred of individuals who were going to undergo colonoscopy were tested for GFOBT and FIT in feces in advance, and 20 µg/g was used as the threshold for determining positive FIT result. The results were analyzed and compared with the results of colonoscopy. **Results:** The sensitivity of FIT to the diagnosis of colorectal cancer was 80.95%, and the specificity was 86.54%. The positive predictive values of FIT test in colorectal cancer screening were 53.1% and 81.77%, respectively. **Conclusion:** FIT is more sensitive and specific for detecting colorectal cancer and adenoma. The fecal occult blood test (FOBT) is stronger, and FIT test detection is more valuable in colon cancer screening.

Keywords: Colonoscopy; Fecal immunochemical test; Colorectal cancer screening

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At present, most of the experimental diagnosis of colorectal cancer are difficult to meet the requirements of sensitivity, specificity, simplicity, and economical and practical methods for colorectal cancer screening in the population. The latest fecal immunochemical detection technique can quantify hemoglobin in feces. The present study will use this technique to perform fecal immunochemical test (FIT) and fecal occult blood test (FOBT), and the results were compared with those of colonoscopy and pathological examination.

1 Materials and methods

1.1 General information

300 patients from the First People's Hospital of Yinchuan and the People's Hospital of the Autonomous Region between December 2015 and November 2018 were selected and recruited for colonoscopy. The patients were 30 – 80 years old, with an average age of 52.67 ± 16.35 years. There were 209 male cases and 91 female cases.

1.2 Research methods

Before the colonoscopy, the patients were tested for FOBT and FIT, and the results were recorded. After the routine bowel cleansing, the colonoscopy was performed the next day, and the pathological biopsy of polyps and suspicious cancerous tissue was performed. The FOBT kit and detection method were used for

testing in accordance with the routine standards of the central laboratory. The FIT kit was purchased from Xi'an Bolcheng Biotechnology Co., Ltd., and it was exclusively imported by the US Enterix company which patented the occult blood test product called InSure-FIT™. The mechanism of FIT is described in the following: The normal 24-hour gastrointestinal physiological blood loss is 0.6 mL, and the blood loss is construed as a pathological bleeding if it is more than 2 mL daily. This method uses colloidal gold immunochromatographic detection for hemoglobin, which mainly detects lower gastrointestinal bleeding, and can be used as an important detection test for early screening of colorectal cancer.

1.3 Electronic colonoscopy

Electronic colonoscopy was conducted by the gastroenterologists in the First People's Hospital of Yinchuan and the People's Hospital of the Autonomous Region using the Olympus260 electronic colonoscopy (from Japan).

1.4 Statistical analysis

Statistical Package for Social Sciences (SPSS), version 13.0, was used for statistical data analyses. The comparison of categorical data was performed using Chi-squared test. The quantitative data was expressed

by ($x \pm s$). The comparison between two or more groups was analyzed by one-way analysis of variance (ANOVA). If the data were normally distributed, the data were analyzed using Pearson's correlation test. Otherwise, the data were analyzed using Spearman rank-order correlation test. $P < 0.05$ was considered statistically significant. The sensitivity, specificity, positive predictive value, and negative predictive value of FIT in colorectal cancer were calculated according to standard formulas.

2 Results

2.1 Comparison of FIT positive predictive rates in colorectal cancer group, colorectal adenoma group and normal group

The FIT positive rates of the colorectal cancer group and the colorectal adenoma group were 80% and 45% respectively. The difference was statistically significant ($P < 0.05$). The FIT positive rate of the normal group was 2%. After comparison, the difference the colorectal cancer group and normal group was statistically significant ($P < 0.05$). The FIT positive rate of colorectal adenoma group was compared with the that of normal group, and the difference was statistically significant ($P < 0.05$). (Table 1).

Table 1. Comparison of FIT positive rates in colorectal cancer group, colorectal adenoma group and normal group

Group	n	FIT positive	FIT negative
Colorectal cancer group	42	34	8
Colorectal adenoma group	63	28	35
Normal group	195	2	193
Chi-squared statistics		5.35	4.26
P-value		<0.05	<0.05

2.2 Comparison of FIT values between colorectal cancer group and colorectal adenoma group

There was a statistically significant difference in FIT values between the colorectal cancer group and the colorectal adenoma group ($P < 0.05$), and a significant

difference in the FIT values between the colorectal cancer group and the normal group ($P < 0.05$). The FIT values between the colorectal adenoma group and the normal group is statistically significant ($P < 0.05$). (Table 2).

Table 2. Comparison of FIT values in colorectal cancer group, colorectal adenoma group and normal group ($x \pm s$)

Group	n	FIT values
Colorectal cancer group	42	67.0 ± 11.3
Colorectal adenoma group	63	32.0 ± 10.6
Normal group	195	14.0 ± 1.3

2.3 Comparison of FOBT positive rates and FIT positive rates between colorectal cancer group, colorectal adenoma group and normal group

The positive rates of FOBT in colorectal cancer group, colorectal adenoma group, and normal group were 24%, 12% and 10% respectively. Pairwise comparison was conducted. The differences were not of statistical significance ($P > 0.05$). (Table 3).

Table 3. Comparison of FOBT positive rates and FIT positive rates between colorectal cancer group, colorectal adenoma group and normal group

Group	n	FOBT positive	FOBT negative
Colorectal cancer group	42	10	32
Colorectal adenoma group	63	7	56
Normal group	195	62	133

2.4 The sensitivity and specificity of FIT in the diagnosis of colorectal cancer was 80.95% and 86.54% respectively. The positive predictive value was 53.1 and the negative predictive value was 81.77. (Table 4).

Table 4. Sensitivity and specificity of FIT for colorectal cancer diagnosis

Group	n	Sensitivity (%)	Specificity (%)	Positive predictive rate	Negative predictive rate
Colorectal cancer group	42	80.95	86.54	53.1	81.77
Colorectal adenoma group	63	44.44	98.98	93.3	86.84

3 Discussion

Colorectal cancer accounts for the fourth highest incidence of cancer in Ningxia region^[1]. The general survey of asymptomatic colorectal cancer is the main means of preventing and treating colorectal cancer. The survey can help detect colorectal cancer and precancerous lesions early, and achieve treatment through early treatment. For the purpose of prevention, the current census methods in our district mostly use one or two methods to screen for high-risk individuals and then perform enteroscopy, but the results are not very satisfactory. Although the fecal occult blood test can reduce the mortality of colorectal cancer by 15%-33% every year or every two years as confirmed that randomized controlled trials, the fecal occult blood test can only detect about 13%-50% of colorectal cancer patients in asymptomatic people^[2-4]. In addition, fewer people can be persistent to go for fecal occult blood test screening regularly, which limits the effectiveness of the fecal occult blood test as a screening method. In recent years, as a highly sensitive and specific method, fecal immunochemical test has attracted attention and is considered to have high application value. Studies abroad have shown that the sensitivity of fecal immunochemical test to diagnosis is 79% and the specificity is 94%. Fecal immunochemical test has an overall diagnostic accuracy of 95% for colorectal cancer. In the United States, Europe, and Asia, this test has begun to replace the fecal occult blood test in national screening programs^[5-12].

In the present study, fecal immunochemical test of hemoglobin was applied for detection in 300 research subjects who were going to undergo colonoscopy. After the completion of colonoscopy and diagnosis, the fecal hemoglobin amount of colorectal cancer patients,

colorectal adenoma patients and normal patients were compared and analyzed. The analysis results showed that when the FIT value was 20 $\mu\text{g/g}$ as the positive threshold, the sensitivity of FIT to diagnose colorectal cancer was 80.95% and the specificity 86.54%. The positive predictive value was 53.1, the negative predictive value was 81.77, and the FIT value of the colorectal cancer group was higher than that of the colorectal adenoma group.

Therefore, we believe that FIT technique can be an important and relatively accurate complementary method for simple colonoscopy or FIT-colonoscopy screening, which can take advantage of its economy, simplicity, acceptability of the subject and good social tolerance. Using FIT as the initial screening test for colorectal cancer can optimize the screening plan, which can improve the screening and diagnosis of colorectal cancer.

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