

Digestive Endoscopy

Fecal hemoglobin concentration is useful for risk stratification of advanced colorectal neoplasia



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ABSTRACT

Background: Although a fecal immunochemical test (FIT) allows quantitation of fecal hemoglobin (f-Hb), it is typically used as a binary result to identify subjects above a predetermined cut-off concentration.

Aims: To investigate whether f-Hb concentration is useful for risk stratification of advanced colorectal neoplasia (CRN).

Methods: This was a retrospective study conducted in a university hospital in Korea. Of 34,547 participants who underwent FIT from June 2013 to May 2015, 1532 (4.4%) showed positive results (≥ 100 ng Hb/ml). Of participants with positive results, 738 subjects aged ≥ 50 years who underwent colonoscopy were analyzed.

Results: Increasing quartile of f-Hb concentration (Q4 vs. Q1; odds ratio, 3.87; 95% confidence interval, 2.36–6.34), as well as older age, male sex, smoking, and metabolic syndrome (MetS), was significantly associated with a higher prevalence of advanced CRN. Risk for advanced CRN increased 5.13-, 4.27-, 5.12-, and 7.15-fold, respectively, among individuals with f-Hb in the fourth quartile who had risk factors such as age ≥ 70 years, male sex, smoking, and MetS compared with individuals with first quartile levels of f-Hb who did not have those risk factors.

Conclusion: In addition to age, sex, smoking status, and MetS, f-Hb concentration in individuals with positive results from FIT can be used to stratify the probability of detection of advanced CRN.

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1. Introduction

Although colorectal cancer (CRC)-associated mortality has been effectively reduced by removing precursor lesions [1], CRC remains the third most common cancer in Western countries [2] and its incidence is rapidly increasing, especially in Asian countries including Korea [3,4]. Therefore, prevention and early detection of CRC has emerged as an important global issue of substantial interest.

Many countries, including Korea and several in Europe, have introduced population-based screening programs based on fecal blood tests that have been developed to detect unnoticeable bleeding from colorectal neoplasia (CRN). Annual screening with fecal blood tests has proved to be an effective method for detecting a majority of CRN in the asymptomatic population and reducing

the mortality of CRC [5,6]. Several studies have reported that the fecal immunochemical test (FIT) is superior to the guaiac-based fecal occult blood test (gFOBT) with respect to the detection rate of advanced CRN (higher sensitivity and higher specificity, and lower frequency of false-positive results) [7–11]. Consequently, FIT is becoming a widely favored option for replacing gFOBT.

FITs allow the quantitation of fecal hemoglobin (f-Hb) concentration. However, in almost all screening programs this is used as a binary result (“negative” or “positive”) to identify subjects with levels above a predetermined cut-off concentration chosen to suit the requirements of colonoscopy. Recently, some studies have showed that f-Hb concentration is related to the severity of CRN [12–15]. Based on the results of those studies, we speculated that f-Hb concentration might be useful for risk stratification for advanced CRN. However, data regarding the clinical significance and application of quantitative data from the FIT in risk stratification for CRC screening are extremely limited. To date, only a few studies have investigated this issue [16,17]. Moreover, quantitative f-Hb concentrations in combination with previously known risk factors for CRN such as older age, male gender, and smoking may contribute

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to identifying individuals with a higher risk for advanced CRN. The present study investigated whether f-Hb concentration, in addition to demographic characteristics, was associated with risk for advanced CRN.

2. Patients and methods

2.1. Study population

This retrospective study consisted of participants who underwent FIT as part of a comprehensive health screening program at Kangbuk Samsung Hospital in Korea from June 2013 to May 2015. Of 34,547 participants who underwent FIT, 1532 (4.4%) showed positive results (≥ 100 ng Hb/ml). Of the participants with positive results, 770 underwent colonoscopy.

For the 770 patients who underwent colonoscopy, exclusion criteria were as follows: previous history of CRC or colorectal surgery ($n=14$), a history of inflammatory bowel disease ($n=7$), incomplete colonoscopy ($n=6$) such as colonoscopy in which the cecum was not reached ($n=1$), inadequate bowel preparation ($n=3$), lack of adequate biopsy ($n=2$), and subjects younger than 50 years ($n=5$). Finally, the total number of eligible subjects for the study was 738 (Fig. 1).

This study was approved by the Institutional Review Board of Kangbuk Samsung Hospital, which exempted the requirement for informed consent because we only assessed deidentified data.

2.2. Measurements and definitions

Data on medical history and health-related behavior were collected through a self-administered questionnaire whereas physical measurements and laboratory tests were performed by trained staff. Blood samples were collected from the antecubital vein after at least a 10-hour fast. Serum levels of total cholesterol and triglycerides were determined using an enzymatic colorimetric assay. Serum fasting glucose levels were measured using the hexokinase method. Blood pressure (BP) and waist circumference were measured by trained staff. For BP measurements, the average of two measurements was used for the data analysis.

Body mass index (BMI) was calculated by dividing measured weight (kg) by height squared (m^2). Obesity was defined as BMI ≥ 25 kg/ m^2 , the proposed cut-off for the diagnosis of

obesity in Asians [18]. Metabolic syndrome (MetS) was diagnosed if three or more of the following criteria were satisfied: abdominal obesity (≥ 90 cm in Asian men and ≥ 80 cm in Asian women), elevated fasting blood glucose (FBG) levels (≥ 100 mg/dL or taking glucose-lowering medications), elevated BP (≥ 130 mmHg systolic, ≥ 85 mmHg diastolic, or taking antihypertensive drugs), elevated triglyceride levels (≥ 150 mg/dL), and reduced high-density lipoprotein cholesterol levels (<40 mg/dL in men and <50 mg/dL in women) [19].

2.3. Fecal immunochemical test

Each participant was instructed on how to collect their fecal sample at the screening center and no dietary or medication restrictions were advised. The collected fecal material was placed in a sampling tube (Elken Chemoical Company, Tokyo, Japan) containing 2.0 ml of buffer designed to minimize the degradation of Hb and sent to the laboratory sealed in a plastic bag. Quantitation of f-Hb was performed using OC-SENSOR DIANA (Elken Chemoical Company, Tokyo, Japan), an immunoassay-based test that uses rabbit polyclonal antibodies to detect Hb in faeces. This test is a turbidimetric latex agglutination test in which Hb present in the patient sample combines with latex-coated antibody to cause a change in absorbance. A light beam is passed through the reaction cells and changes in the intensity of the light beam are measured. Testing is performed on an automated analyzer and qualitative results are generated. Results of FIT are expressed in nanograms of Hb per milliliter of buffer and OC-SENSOR, the most widely used quantitative FIT, commonly applies a cut-off of 100 ng Hb per mL buffer (equivalent to 20 micrograms of Hb per gram of faeces) [20]. We performed a regular calibration analysis once a month and regular quality control analysis with two levels of control materials every working day using materials provided by the manufacturer.

2.4. Colonoscopy and histologic examination

Colonoscopy was performed by experienced (>1000 cases) gastroenterologists using an EVIS LUCERA CV-260 colonoscope (Olympus). All examinees took 4 L of polyethylene glycol solution for bowel preparation. All detected polypoid lesions were biopsied or removed and histologically assessed by experienced pathologists.

Polyps were classified by number, size, and histologic characteristics (tubular, tubulovillous, or villous adenoma; hyperplastic polyp; sessile serrated adenoma or traditional serrated adenoma). Pathologic results of hyperplastic polyps or inflammatory polyps were considered normal findings. The grade of dysplasia was classified as low or high. Advanced adenoma was defined as the presence of one of the following features: >10 mm in diameter, tubulovillous or villous structure, and high-grade dysplasia (HGD). High-risk adenoma (HRA) was defined as advanced adenoma or three or more adenomas. Advanced CRN was defined as a cancer or advanced adenoma, and overall CRN was defined as a cancer or any adenoma.

2.5. Statistical analysis

Data are expressed as mean \pm standard deviation or frequency (%). Baseline characteristics according to the quartiles of f-Hb concentration were compared by chi square analysis or Fisher's exact test for categorical variables and by one-way ANOVA for continuous variables. We compared median f-Hb in patients with and without colorectal lesions using the Mann Whitney *U*-test. Colonoscopic/histologic findings according to the quartiles of f-Hb concentration were evaluated using linear by linear association.

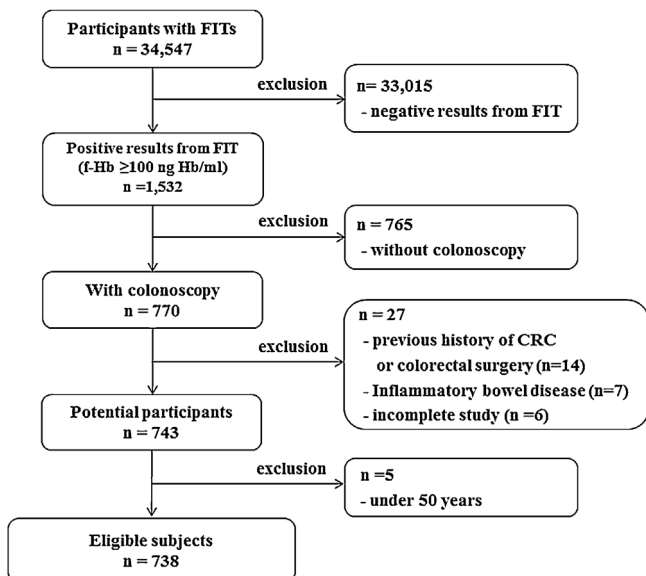


Fig. 1. Flow diagram illustrating the selection of study subjects.

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