



# How Effective is a Fecal Occult Blood Test to Detect Malignancy?

## Maligniteyi Saptamak için Gaitada Gizli Kan Testi Ne Kadar Etkilidir?

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### ABSTRACT

**Aim:** Cancer, an important public global health problem, is the second leading cause of death after cardiovascular diseases. We aimed to reveal the incidence of colorectal cancer (CRC) by the positive fecal occult blood test (FOBT), requested within the scope of periodic health examination (PHE) in patients applied to the family medicine outpatient clinic.

**Materials and Methods:** A total of 119 people aged between 50 and 70 years, who applied to the family medicine outpatient clinic of a university hospital for general health check-up, were included in the study. A questionnaire, in which socio-demographic data and CRC risk factors were questioned, was applied to the participants. The hemogram, FOBT, colonoscopy, and the pathology results of the patients were evaluated.

**Results:** Of 119 participants, 62 (52.1%) were female and 57 (47.9%) were male. The mean age of the participants was 61.0±7.6 years. FOBT was found to be positive in 65 (54.6%) of all participants. Five people (4.2%) who participated in the study were diagnosed with CRC according to the biopsy results obtained during the colonoscopy procedure. In our study, the rate of malignancy detection in all patients with positive FOBT including CRC diagnosis was found to be 7.7% (n=5). Our study detected statistically significant relationships between FOBT positivity and diagnosis of CRC.

**Conclusion:** Following the appropriate recommendations of PHE guidelines and CRC screenings in individuals with high-risk levels, FOBT contributes to early diagnosis and referral to treatment as soon as possible.

**Keywords:** Colorectal cancer, fecal occult blood test, cancer screening, periodic health examination

### ÖZ

**Amaç:** Kanser, kalp damar hastalıklarından sonra ikinci önde gelen ölüm nedeni ve önemli bir halk sağlığı sorunudur. Aile hekimliği polikliniğine başvuran hastalarda periyodik sağlık muayenesi (PSM) kapsamında istenen gaitada gizli kan test (GGKT) pozitifliklerinde kolorektal kanser (KRK) görülme sıklığını ortaya koymayı amaçladık.

**Gereç ve Yöntem:** Çalışmaya bir üniversite hastanesinin aile hekimliği polikliniğine genel sağlık kontrolü için başvuran 50-70 yaş arasındaki 119 kişi dahil edildi. Katılımcılara sosyo-demografik verilerin ve KRK risk faktörlerinin sorgulandığı bir anket uygulandı. Hastaların hemogram, GGKT, kolonoskopi sonuçları ve patoloji sonuçları değerlendirildi.

**Bulgular:** Araştırmaya katılan 119 kişinin 62'si (%52,1) kadın, 57'si (%47,9) erkekti. Katılımcıların yaş ortalaması 61,0±7,6 yıl idi. Tüm katılımcılardan 65 kişinin (%54,6) GGKT'si pozitif saptandı. Araştırmaya katılan 5 kişiye (%4,2) kolonoskopi işleminde alınan biyopsi sonuç raporlarına göre KRK tanısı konuldu. KRK tanısı konan 5 kişinin GGKT sonucu pozitif olup, GGKT pozitif çıkan tüm hastalardaki malignite saptanma oranı, araştırmamızda %7,7 (n=5) olarak bulundu. Çalışmamızda GGKT pozitifliği ve KRK tanısı arasında istatistiksel olarak anlamlı bir ilişki saptandı.

**Sonuç:** Birinci basamak PSM kılavuzlarının uygun önerileri doğrultusunda ve risk düzeyi yüksek olan bireylerde KRK taramalarında, GGKT erken tanı koyması ve en kısa sürede tedaviye yönlendirmesine katkı sağlamaktadır.

**Anahtar Kelimeler:** Kolorektal kanser, gaitada gizli kan testi, kanser taraması, periyodik sağlık muayenesi

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## INTRODUCTION

Cancer is the second leading cause of death and disease in Turkey after cardiovascular diseases as an important public health problem<sup>1</sup>. Cancer, in which environmental factors and genetic predisposition play a role together, differs from geographical, economic, social, and cultural reasons. In addition, epidemiological studies show that the frequency of colorectal cancer (CRC) increases in lifestyle changes such as obesity, red/processed meat consumption, tobacco and alcohol use. However, the pleasing part for some types of cancer is that they can be prevented by inexpensive and easily applicable methods<sup>2</sup>.

CRC is the third most common cancer diagnosed in men and the second most common in women. Over the years, CRC grows slowly from premalignant lesions before transforming into a malignant form. CRC is suitable in screening for early diagnosis, as the colon and rectum are easy-to-scan organs in cancer screenings<sup>3</sup>. Studies have proven that CRC screening methods are effective in reducing cancer incidence and mortality. Screening methods of CRC include a fecal occult blood test (FOBT), rectosigmoid colonoscopy, colonoscopy, double-contrast barium enema, and computed tomography colonography. In particular, some studies have shown that FOBT can reduce mortality by 1/3<sup>4</sup>.

Periodic health examination (PHE) is the evaluation of people who are not sick or have no signs of disease according to age, sex, and risk factors, through screening, examination, and tests with evidence-based structured, effective, specific, acceptable, and applicable follow-up plans<sup>5</sup>. PHE is recommended to follow-up and screen to detect precancerous lesions or early-stage tumors at regular intervals in non-patients in primary care. Thus, PHE aims to reduce the morbidity and mortality of healthy individuals by identifying the early stages symptoms and risk factors of preventable and treatable diseases. In our country, breast cancer, cervical cancer, and CRC are screened within the scope of PHE<sup>6</sup>. It is recommended that all men and women between the ages of 50 and 75 years, who are the target population, be screened for CRC once a year with FOBT and once every 10 years by colonoscopy<sup>5</sup>.

Family physicians (FPs) are obliged to provide comprehensive and continuous personal preventive health services and primary diagnosis, treatment, and rehabilitative health services for everyone regardless of age, sex and disease. Therefore, FP fulfills one step of preventive health services with PHE<sup>7</sup>. In our study, we aimed to reveal the incidence of CRC in patients with FOBT positivity within the scope of PHE in patients who applied to the Family Medicine Outpatient Clinic.

## MATERIALS AND METHODS

The study was prospectively planned in 119 volunteers who applied to a Tekirdağ Namık Kemal University Hospital Family Medicine Outpatients Clinic between October 2020 and March 2021, with the approval of the Ethics Committee (protocol no: 2020.168.07.01). People with a cancer diagnosis or colon disease and/or a history of upper gastrointestinal tract erosion or ulcer were not included in the study. In addition, people using antiaggregant, anticoagulant and non-steroidal anti-inflammatory drugs were among the exclusion criteria in our study. After getting informed consent, the healthy volunteers between the ages of 50 and 70 years were tested for FOBT within the scope of PHE. The FOBT was performed with the commercial FOB rapid test cassette (Feces)/citest kit. The occult blood was measured by rapid chromatographic card test and qualitative lateral flow immunoassay. It measures the occult blood in the stool over 50 ng/mL or 6 ug/g with the double sandwich technique. The test line has anti-hemoglobin (Hb) antibodies. Colored line formation indicates a positive result. The stool sample was collected in a clean container and studied within 6 hours. After mixing the buffer with the stool, the result was evaluated in 5 minutes. Relative sensitivity was 95% [95% confidence interval (CI): 91-97.6%], relative specificity was 98.6% [95% CI: (97.7%-99.2%)], and precision within- and between-run was >99%<sup>8</sup>.

The questionnaire prepared by the researchers, which questioned socio-demographic data of the patients, chronic diseases, treatments, risk factors, and common symptoms of CRC, was administered to the participants face-to-face. A FOBT sample was requested 3 times from each participant. The test is not affected by diet. People give samples without taking alcohol and aspirin or other drugs for 48 hours. Participants, who gave consent for CRC screening, were then referred to the endoscopy unit for colonoscopy. Colonoscopy procedures to the entire colorectal region of the patients were performed by a gastroenterology specialist. Biopsy was taken from the lesions during colonoscopy and transferred to pathological examination. The participants were evaluated for Hb value, colonoscopy, pathology, and FOBT results according to the questionnaire form.

### Statistical Analysis

The Kolmogorov-Smirnov test was performed in all groups and parametric/non-parametric distribution of parameters was determined. To examine the difference in parameters between the groups, the Student's t-test was used for tests with parametric distribution and the Mann-Whitney U test was used for tests with the non-parametric distribution. The categorical variables were analyzed using the chi-square test.

All statistical analyses were performed with the SPSS 18.0 (SPSS Inc., Chicago, IL) program, and p-values less than 0.05 were considered statistically significant.

## RESULTS

Out of a total of 119 people in the research group, 62 (52.1%) were female and 57 (47.9%) were male. The mean age of the study group was 61.0±7.6 years (the mean age was 60.82±7.22 years for women and 61.28±7.99 years for men). There was no statistically significant difference between male and female genders in 46.2% (n=55) of patients aged 60 years and younger and 53.8% (n=64) of patients over 60 years of age (p>0.05) (Table 1). Considering the FOBT results of the participants, the tests of 65 people (54.6%) were positive and the tests of 54 people (45.4%) were negative (Figure 1).

When the relationship between socio-demographic characteristics and occult blood tests were evaluated, there was no statistical significance between age, gender, exercise, smoking-alcohol use, occupational status, and income level of individuals, and FOBT positivity. When we looked at FOBT positivity according to the BMI of the participants, a statistically significant relationship was determined with the FOBT positivity of the group with overweight/obese (p=0.023). When we questioned the dietary habits of the participants, FOBT positivity was significantly higher in the group with high animal food consumption than in the low consumption group. (p=0.029) (Table 1).

As a result of the colonoscopy procedure applied to all participants, no pathology was detected in 54 people (45.4%) and the most common pathology was colon polyps in 29

people (24.4%). According to the results of the colonoscopy report after the procedure, four people (3.4%) were pre-diagnosed with tumors. When the results of pathology samples taken during colonoscopy were evaluated, five people (4.2%) received the main diagnosis of CRC (Table 2).

Considering the colonoscopy report results and FOBT results of 119 patients who underwent colonoscopy, the incidence of FOBT positivity was statistically significantly higher in the group with lesions than in the group without lesions (p<0.001). FOBT positivity rates after colonoscopy were statistically significantly higher in the group with lesions compared to the group without lesions (p=0.017) (Table 3).

## DISCUSSION

CRC is a largely treatable disease if diagnosed at an early stage. Early diagnosis of the disease is possible by screening people in the asymptomatic stage<sup>9</sup>. For this purpose, FOBT is an appropriate screening test in our country and reduces the need for colonoscopy<sup>10</sup>.

According to the FOBT result applied to 119 people in our study, 65 people (54.6%) were tested as positive. In the study conducted by Levi et al.<sup>11</sup> on 16,359 people, of the 2.266 participants undergoing FOBT, 88 (3.9%) tests were positive. In many similar studies, FOBT positivity rates were found to be lower than in our study<sup>12-14</sup>. We can attribute the higher rate of FOBT positives in our results, compared to other studies, to the fact that our target group screened with PHE consisted of people aged 50 and over. However, epidemiological studies with larger participation are needed.

In our study, 50.8% of the participants who were positive for FOBT were female and 49.2% were male. In a similar study by Demiral et al.<sup>15</sup>, 48.6% of those with positive FOBT results were female and 51.4% were male. In both studies, the rates of FOBT positivity and FOBT positivity according to gender were similar, and gender had no effect on the test result. Contrary to our study, in the study of Kara et al.<sup>16</sup>, 60% of the 300 patients with positive FOBT were female and 40% were male, and they found the rate of test positivity higher in females.

In our study, no pathology was detected with colonoscopy in 21.5% of FOBT positive patients. In other similar studies, 75.7% of patients tested positive for FOBT were reported normal with colonoscopy, which was much higher than in our study<sup>12,15,17</sup>. In other studies similar to our findings, even pathological lesions were not detected in people with FOBT positive<sup>18,19</sup>. In our study, at least one lesion was detected in 78.5% of the patients in the colonoscopy performed on FOBT positive patients. The reason for the higher incidence of pathological lesions in our study can be attributed to the fact that the screened group was 50 years or older.

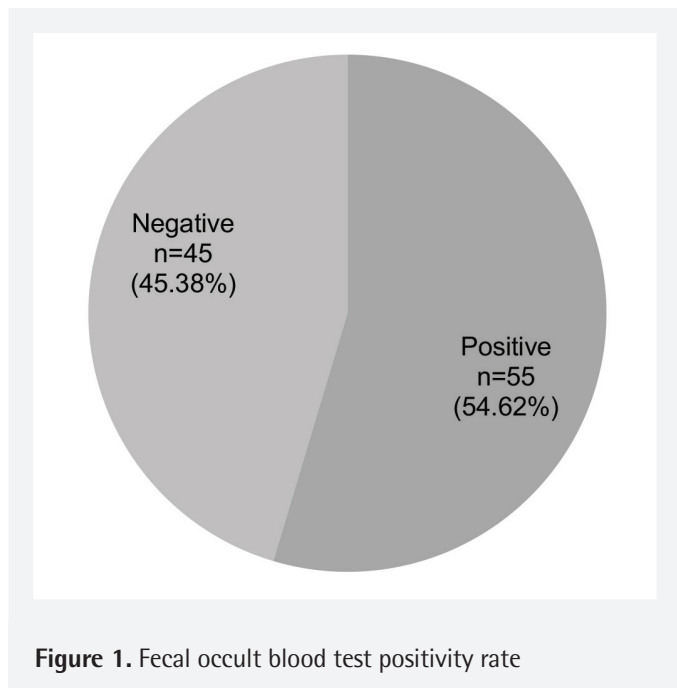


Figure 1. Fecal occult blood test positivity rate

When we looked at the pathology results of our patients, whose FOBT results were positive, CRC was detected in 7.7% of the patients. Quyn et al.<sup>20</sup>. reported a 7.1% CRC detection rate in their series of 53,332 cases of FOBT positivity in the screening group, and our findings were similar to several similar studies<sup>12,18</sup>. There are also studies with a lower rate of CRC compared to our study<sup>15,16,19</sup>.

In our study, CRC was detected in five people (4.2%) according to the colonoscopy results of all participants and no pathology was detected in 54 people (45.4%). In the study, conducted by Yaşar<sup>21</sup>, CRC was found in 3.9% of people according to the results of colonoscopy, and no pathology was detected in 42.9%. When we compared our study with similar studies, the percentages of CRC were close to each other and our

results were similar to the literature in this sense<sup>22,23</sup>. We can attribute the differences in studies to the diversity of genetic and environmental factors, dietary changes, the frequency of familial CRC syndromes (such as FAP), and lower cancer screening rates in some countries.

**Study Limitations**

The research population is limited to 119 individuals applying to Tekirdağ Namık Kemal University Faculty of Medicine, Department of Family Medicine Outpatient Clinic.

**CONCLUSION**

In our study, FOBT was positive in patients diagnosed with CRC and there was a statistically significant relationship

**Table 1. The relationship between the socio-demographic characteristics and habits of the participants and the results of the fecal occult blood test**

Socio-demographic data		Fecal occult blood test		Total (%)	p
		Positive n (%)	Negative n (%)		
Gender	Female	33 (50.8)	29 (53.7)	62 (52.1)	0.750
	Male	32 (49.2)	25 (46.3)	57 (47.9)	
Age (years)	50-60	32 (49.2)	23 (42.6)	55 (46.2)	0.470
	61-70	33 (50.8)	31 (57.4)	64 (53.8)	
Body mass index	Normal	15 (23.1)	23 (42.6)	38 (31.9)	0.023*
	Overweight/obese	50 (76.9)	31 (57.4)	81 (68.1)	
Exercise	Yes	27 (41.5)	21 (38.9)	48 (40.3)	0.769
	No	38 (58.5)	33 (61.1)	71 (59.7)	
Smoking	Yes	15 (23.1)	8 (14.8)	23 (19.3)	0.116
	No	31 (47.7)	36 (66.7)	67 (56.3)	
	Quit	19 (29.2)	10 (18.5)	29 (24.4)	
Alcohol use	Yes	7 (10.8)	6 (11.1)	13 (10.9)	0.913
	No	56 (86.2)	47 (87.0)	103 (86.6)	
	Quit	2 (3.1)	1 (1.9)	3 (2.5)	
Animal food consumption	Rarely	4 (6.2)	5 (9.3)	9 (7.6)	0.029*
	Sometimes	30 (46.2)	36 (66.7)	66 (55.5)	
	Often	31 (47.7)	13 (24.1)	44 (37.0)	
Family history of IBD CRC in family history	Yes	5 (7.7)	1 (1.9)	6 (5.0)	0.147
	No	60 (92.3)	53 (98.1)	113 (95.0)	

\* p<0.05, IBD: Irritable bowel disease, CRC: Colorectal cancer

**Table 2. Lesions detected in participants according to colonoscopy and pathology results**

According to colonoscopy results	n (%)	According to the pathology results	n (%)
Polyp	29 (24.4)	Adenomatous polyp	11 (9.2)
Inflammation	16 (13.4)	Inflammation	19 (16.0)
Hemorrhoids	12 (10.1)	Hyperplastic polyp	7 (5.9)
Tumor	4 (3.4)	Malignancy	5 (4.2)
Angiodysplasia	2 (1.7)	Tubular adenoma	9 (7.6)
Ulcerated lesion	2 (1.7)	Adenomatous polyp	11 (9.2)

**Table 3. The relationship between the colonoscopy and pathology results of the participants and the result of the fecal occult blood test**

		Fecal occult blood test		Total (%)	p
		Positive n (%)	Negative n (%)		
Colonoscopy result	Polyp	18 (27.7)	11 (20.4)	29 (24.4)	0.000**
	Inflammation	14 (21.5)	2 (3.7)	16 (13.4)	
	Hemorrhoids	12 (18.5)	0 (0.0)	12 (10.1)	
	Tumor	4 (6.2)	0 (0.0)	4 (3.4)	
	Angiodysplasia	2 (3.1)	0 (0.0)	2 (1.7)	
	Ulcerated area	1 (1.5)	1 (1.9)	2 (1.7)	
	Natural	14 (21.5)	40 (74.1)	54 (45.4)	
Pathology result	Inflammation	17 (44.7)	2 (15.4)	19 (37.3)	0.017*
	Adenomatous polyp	8 (21.1)	3 (23.1)	11 (21.6)	
	Malignancy	5 (13.2)	0 (0.0)	5 (9.8)	
	Tubular adenoma	6 (15.8)	3 (23.1)	9 (17.6)	
	Hyperplastic adenoma	2 (5.3)	5 (38.5)	7 (13.7)	

\*p&lt;0.05, \*\*p&lt;0.001

between FOBT positivity and malignancy diagnosis. FOBT, which is evaluated in our country with the clinical findings and the age of the patient in cancer screenings carried out within the scope of PHE, has an important place in reducing mortality and morbidity by early diagnosis of CRC. Screening of the registered population by FPs in terms of risk factors and ensuring protection before disease occurs is the key for preventive medicine in terms of informing people about cancer screening programs. As FPs, we should provide education to the population we follow about cancer screenings and counseling on predisposing causes such as obesity, nutrition, smoking and alcohol use that play a role in the etiology of CRC.

### Ethics

**Ethics Committee Approval:** Ethics committee approval was obtained from Tekirdağ Namık Kemal University Ethics Committee (protocol no: 2020.168.07.01, date: 28.07.2020).

**Informed Consent:** It was planned prospectively on 119 volunteers who applied to the family medicine outpatient clinic of a university hospital between October 2020 and March 2021.

**Peer-review:** Externally peer-reviewed.

### Authorship Contributions

Surgical and Medical Practices: T.A.Ş., E.Ç.G., R.M., Concept: T.A.Ş., E.Ç.G., Design: T.A.Ş., E.Ç.G., R.M., Data Collection or Processing: T.A.Ş., E.Ç.G., R.M., Analysis or Interpretation: T.A.Ş., E.Ç.G., Literature Search: T.A.Ş., E.Ç.G., Writing: T.A.Ş., E.Ç.G.

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