# The Use of Immunochemical Fecal Occult Blood Test as Colorectal Cancer Screening Tool in Asymptomatic Population in Indonesia

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## ABSTRACT

**Background:** Colorectal cancer is the fourth leading cause of cancer-related mortality worldwide. Early detection of colorectal cancer is necessary in term of increasing survival. Immunochemical fecal occult blood test (I-FOBT) is one of the simple and inexpensive screening modality that can be used widely. No data has been available yet regarding the usage of I-FOBT in Indonesia. This study is a prevalence study of I-FOBT in asymptomatic population in Indonesia.

**Method:** A cross sectional study was conducted in asymptomatic population visiting five public health service centers in Depok district, West Java, Indonesia. This study was performed from January to March 2012. Case report form and I-FOBT kit were used to assess and screen the patients. Statistic analysis was performed using Chi-square test.

**Results:** The prevalence of positive I-FOBT was almost equally distributed among age group. Female dominated whole patients 202 (72.7%). Most of them had middle to low education level 116 (41.7%). As many as 50.7% patients had normal body mass index. We had 11 (4%) patients with positive result of I-FOBT.

*Conclusion:* Prevalence of positive result of I-FOBT in asymptomatic population in Indonesia was 4%. Further studies were needed to confirm sensitivity and specifity of I-FOBT in Indonesia.

Keywords: colorectal cancer, immunochemical fecal occult blood test (I-FOBT), early detection

## ABSTRAK

Latar belakang: Kanker kolorektal merupakan penyebab keempat terbanyak kematian akibat kanker di dunia. Deteksi dini kanker kolorektal diperlukan untuk meningkatkan kesintasan. Immunochemical fecal occult blood test (I-FOBT) adalah modalitas uji penapisan sederhana dan murah yang dapat digunakan secara luas. Belum terdapat data mengenai pemanfaatan I-FOBT di Indonesia. Penelitian ini ditujukan untuk melihat prevalensi hasil I-FOBT pada populasi tanpa gejala di Indonesia.

**Metode:** Penelitian potong lintang telah dilakukan pada populasi tanpa gejala yang mengunjungi lima fasilitas pelayanan kesehatan masyarakat di beberapa kecamatan wilayah Depok, Jawa Barat, Indonesia. Penelitian ini dilakukan pada bulan Januari hingga Maret 2012. Formulir laporan kasus dan kit I-FOBT digunakan untuk menilai dan menapis subjek penelitian. Analisis statistik dilakukan dengan menggunakai uji Chi-square.

**Hasil:** Prevalensi I-FOBT positif yang didapat hampir terdistribusi berimbang di setiap kelompok usia. Wanita mendominasi jumlah pasien penelitian 202 (72,7%). Pasien kebanyakan berpendidikan rendah 116 (41,7%). Sebanyak 50,7% pasien memiliki indeks massa tubuh yang normal. Terdapat 11 (4%) pasien yang memberikan hasil uji I-FOBT positif.

*Simpulan:* Prevalensi uji I-FOBT positif pada populasi tanpa gejala di Indonesia adalah 4%. Penelitian lanjutan diperlukan untuk menilai sensitivitas dan spesifisitas uji I-FOBT di Indonesia.

Kata kunci: kanker kolorektal, immunochemical fecal occult blood test (I-FOBT), deteksi dini

## INTRODUCTION

Colorectal cancer (CRC) is the fourth most common malignancy in the world and is considered as a serious medical problem.<sup>1</sup> Data from Globocan 2008 shows that the 5-year prevalence of CRC is the second highest after breast cancer and 609,051 people per year died as a result of the cancer.<sup>1</sup> The mortality rate of CRC from 1985 to 2005 was decreased in several countries.<sup>2</sup> This decrease were due to screening and/or better treatment.<sup>2-5</sup> However, increases in mortality rates are still occurring in countries that may have limited resources, including Mexico and Brazil in South America and Romania and Russia in Eastern Europe, compared with longstanding, economically developed countries.<sup>2</sup> International practical guidelines and expert consensus recommend colorectal cancer screening in individuals older than 50 years old.6 If the cancer were found in the early stage, localized and found in the early stage, study shows that the 5-year survival rate of this cancer may reach up to 95%.7

The fecal occult blood test (FOBT) has been recommended as screening method of colorectal cancer.<sup>8,9</sup> There are two types of test to identify colorectal cancer at early stage: Guaiac FOBT (G-FOBT) and immunochemical FOBT (I-FOBT). However, screening of colorectal cancer using G-FOBT has many disadvantages compared to I-FOBT. The G-FOBT has high false positive value because of the inability to differentiate the source of occult blood along gastrointestinal tract. The G-FOBT also interacts with several foods that create false positive result and three days diet restriction is needed before conducting G-FOBT. Examining patient using I-FOBT does not require diet restriction and more specific in detecting bleeding in the colon and rectum. Hence, the usage of I-FOBT is easier and more comfortable for the patients as it requires only single stool sample. Overall, I-FOBT has better sensitivity and specificity than G-FOBT.<sup>10</sup>

The I-FOBT is considered a novel method for screening of colorectal carcinoma in Indonesia. This method has never been used widely as screening method for early detection of CRC in Indonesia. In limited resources country as Indonesia, simple and affordable test for early detection of colorectal carcinoma is a very important element. For supporting the use of this test in general population in Indonesia, it is important to do a population-based study on asymptomatic population using I-FOBT in the rural setting.

# METHOD

This is a population based survey conducted in five community health centers in Depok district, West Java. It was conducted from January 2012 to February 2012. The target population of this study were those who live in the proximity of the five largest community health centres in Depok. These five community health centres were Beji, Cimanggis, Cipayung, Pancoran Mas and Sukmajaya.

Using cluster consecutive sampling, all patients visited Depok community health centre were included. The inclusion criteria were as follows; patient lived in Depok, aged older than 40 years old and agreed to sign the informed consent. The exclusion criteria were patient with obvious gastrointestinal bleeding, history of colorectal cancer and patient with very soft stool. Patient with obvious gastrointestinal bleeding does not need FOBT, while patient with previous history of colorectal cancer does not need screening, but surveillance. Additionally very soft stool may alter I-FOBT result.

The prediction for sample size was calculated using the population estimation formula with absolute precision, with p = 0.232. The result of this sample size calculation were 212. The feces was examined using I-FOBT method. Those with positive I-FOBT would further undergo colonoscopy examination.

Data analysis were done using SPSS 17.0. Validation processes were done to ensure the integrity of recorded data. Categorical descriptive data was shown in percentage. Numerical and continuous data were shown in the form of average with standard deviation if the distribution was normal, or in the form of median with minimal and maximal value if the distribution was not normal. Descriptive and analytical data were given in narrative tabular and graphical forms.

## RESULTS

All 278 patients from five community health centres at Depok had been collected from January to February 2012. The demographic data were collected and their stool sample were examined for I-FOBT. The distribution of study patients was as follows:



Beji Health Center
Cimanggis Health Center
Cipayung Health Center
Pancoran Mas Health Center
Sukmajaya Health Center

Figure 1. Distribution of patients (n) from five district level community health centres in Depok

From Figure 1 we can see the distribution of the patient throughout the five community health centres was not well distributed. This might be caused by patient's rejection to participate in this study. The reasons varied, including uncomfortable with the study process in which they had to collect stool sample inside a tube, anxious of positive I-FOBT result, busy at work and difficulty in returning the stool sample.

From this study, we found that the prevalence was almost equally distributed among age group, with female dominated (72.7%). The majority of study subjects had primary and secondary school as their last education (41.7%). Almost all of them were married (93.2%) and the occupation of the study participant were mainly housewife (45.3%). Almost half the patient (50.7%) had normal body mass index (BMI).

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Variable	T	otal (%)
Age group (year)		
40-49	102	(36.7%)
50-59	90	(32.3%)
<u>≥</u> 60	86	(31%)
Sex		
Male	76	(27.3%)
Female	202	(72.7%)
Education level		
Uneducated	14	(5%)
Primary and secondary school	116	(41.7%)
High school	93	(33.5%)
University/college	5	(19.8%)
Marital status		
Married	259	(93.2%)
Not married	4	(1.4%)
Divorced-deceased	13	(4.7%)
Divorced	2	(0.7%)
Employment		. ,
Full-time	64	(23%)
Part-time	15	(5.4%)
Housewife	126	(45.3%)
Unemployed	37	(13.3%)
Other	36	(13%)
Monthly earning (IDR)		( )
< 500,000	70	(25.2%)
500,000-1,000,000	54	(19.4%)
1,000,000-5,000,000	108	(38.9%)
> 5,000,000	9	(3.2%)
No answer	37	(13.3%)
Body mass index (kg/m <sup>2</sup> )		· · · ·
Thin (≤ 18.49)	37	(13.3%)
Normal (18.50-24.99)	141	(50.7%)
Overweight (25.00-25.99)	80	(28.8%)
Obese (≥ 30.00)	20	(7.2%)

#### Table 2. Distribution of patient history

Variable	Yes	No
variable	n (%)	n (%)
History of malignancy	8 (2.9%)	270 (97.1%)
Family history of malignancy	35 (12.6%)	240 (86.3%)
Medical history		
Diabetes mellitus	42 (15.1%)	236 (84.9%)
Hypertension	109 39.2%)	169 (60.8%)
Coronary heart disease	23 (8.3%)	255 (91.7%)
Hematoschezia	34 (12.2%)	246 (88.4%)
Diarrhea/constipation	81 (29.1%)	197 (70.9%)
Anemia	24 (8.6%)	254 (91.4%)
Mucoid stool	33 (11.9%)	245 (88.1%)
Stomach/anal pain	69 (24.8%)	209 (74.1%)
Weight loss	23 (8.3%)	255 (91.7%)
Altered bowel habit	30 (10.8%)	248 (89.2%)
Vomiting	24 (8.6%)	254 (91.3%)
Malaise/fatigue	75 (27%)	203 (73%)

## Table 3. Distribution of patients' charateristic with I-FOBT result

	I-FOBT Result			
Variable	Positive	Negative		
	n (%)	n (%)		
Age group (years)				
40-49	2 (2%)	99 (98%)		
50-59	5 (5.7%)	83(94.3%)		
> 60	4 (4.7%)	82 (95.3%)		
Sex				
Male	4 (5.3%)	72 (94.7%)		
Female	7 (3.5%)	195 (96.5%)		
Education level				
Uneducated	0 (0%)	14 (100%)		
Primary and secondary school	5 (4.3%)	111(95.7%)		
High school	5 (5.4%)	88 (94.6%)		
University/college	1 (1.8%)	54 (98.2%)		
Marital status				
Married	11 (4.2%)	248 (95.8%)		
Not married	0 (0%)	4 (100%)		
Divorced-deceased	0 (0%)	13 (100%)		
Divorced	0 (0%)	2 (100%)		
Employment				
Full-time	2 (3.1%)	62 (96.9%)		
Part-time	0 (0%)	15 (100%)		
Housewife	5 (4%)	121 (96%)		
Unemployed	2 (5.4%)	35 (94.6%)		
Other	2 (5.6%)	34 (94.4%)		
Monthly earning (IDR)				
< 500,000	5 (7.1%)	65 (92.9%)		
500,000-1,000,000	2 (3.7%)	52 (96.3%)		
1,000,000-5,000,000	2 (1.9%)	106 (98.1%)		
> 5,000,000	0 (0%)	9 (100%)		
No answer	2 (6.9%)	27 (93.1%)		
Body mass index (kg/m <sup>2</sup> )				
Thin (≤ 18.49)	2 (5.4%)	35 (94.6%)		
Normal (18.50-24.99)	8 (5.7%)	133(94.3%)		
Overweight (25.00-25.99)	1 (1.3%)	79 (98.8%)		
Obese (≥ 30.00)	0 (0%)	20 (100%)		

I-FOBT: immunochemical fecal occult blood test

Eleven asymptomatic patients were found to have positive I-FOBT result (prevalence of 4%), as shown in Figure 2.



Figure 2. I-FOBT results in asymptomatic patients

## DISCUSSION

The age group was equally distributed among patients. Most patients were female (72.7%). Statistics showed 142,672 American diagnosed with colorectal cancer, among 69.917 of them were female.<sup>11</sup> It may be caused by higher health consciousness among female patients. Almost half of the female study patients were housewives, and this gave them more free time compared to men, so they had more time to go to the health centre.

Large proportion of the patients had primary and secondary school as their education level (41.7%). The education level influenced the health literacy, the amount of information understood by patients and the comprehension of information given. In low education level patients, we need to give simpler language when giving explanation about colorectal cancer prevention information and this would lead to higher rate of adherence.

Almost half of the patients had normal BMI (50.7%). Higher BMI will lead to two times fold increasing of colon cancer risk. Lack of physical activity and central obesity were also related to incidence of colon cancer. Moderate to vigorous physical activity will decrease incidence of colon cancer by 4 to 50%.

This study showed interesting findings of previous malignancy history. Eight patients reported positive previous malignancy history, which were cervical cancer, skin cancer, post-hysterectomy uterine fibroid, prostate tumor, sof tissue tumor, lymph node malignancy and breast tumor. The incidence ranged from 1963 to 2009. Thirty five patients had positive family history of malignancy. Beside those factors mentioned above, family history also plays role in incidence of colorectal cancer. Eleven asymptomatic patients were found to have positive I-FOBT result (prevalence of 4%). In the previous study, the sensitivity and specificity of fecal immunochemical test (FIT) in CRC screening in Indonesia using OC Light<sup>®</sup> and Oncoprobe<sup>®</sup> kit were 39.5% vs. 42.1% and 86.4% vs. 81.8% respectively.<sup>12</sup> Those patients with positive I-FOBT were referred for further work-up tests but they did not comply and participate further in the study.

This study is the first epidemiological based study in the topic of early detection of colorectal cancer using I-FOBT. I-FOBT is considered to be new, relatively cheap and easy to perform. The importance of colorectal cancer screening is that early lesion found can increase survival chance of the patient. Unfortunately, colonoscopy evaluation among the positive patients has not been performed in respect to patients' preferences.

## CONCLUSION

The prevalence of positive value of I-FOBT in the asymptomatic population is 4%. Further study should be done to confirm I-FOBT finding with colonoscopy and histopathological test.

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