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Colorectal Cancer Screening Using Immunochemical Faecal Occult Blood test in Perak – A Cross-Sectional Study

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ABSTRACT

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Colorectal cancer (CRC) is the second most common cancer in Malaysia (13.5%).[1] Immunochemical faecal occult blood test (iFOBT) is known to be a newer, simpler, more sensitive, less expensive and non-invasive approach to CRC screening available.[2, 3] The objectives of this study was to describe sociodemographic characteristics, prevalence of positive iFOBT tests and association between positive iFOBT tests, sociodemographic characteristics and colonoscopic findings of detecting CRC in Perak. This was a retrospective cross-sectional study, involving secondary data review of all patients screened for CRC using iFOBT in 96 government health clinics in Perak, from 1/1/2019 until 31/12/2019. Universal sampling method was used. Total of 819 patients were screened. Detailed colonoscopic findings were obtained from database in Perak State Health Department. Mean age was 62.64 (±7.37) years, 50.7% were females and 49.3% were males. Majority of respondents were Malays (57.4%) and iFOBT tests were done in urban government health clinics (67.8%). Out of 819 respondents, 3.1% obtained positive iFOBT results, majority being Malays (1.7%), females (1.6%) with age <65 years old (1.8%). Among the 3.1%, only 4 had pre-cancerous/cancerous lesion colonoscopic findings. Analysis of association between positive iFOBT results, sociodemographic characteristics and colonoscopic findings revealed no significant association between age and gender with colonoscopic findings. There was significant association between ethnicity and colonoscopic findings (p=0.037), however, only 4 tested positive. The detection rate for carcinoma is suboptimal using iFOBT test, probably due to the low numbers screened. Further strengthening of the program is needed to achieve a more favourable outcome.

INTRODUCTION

Colorectal cancer (CRC) is one of the leading causes of cancer-related death in the world.[4] with more than 1.2 million new cases and over 600,000 deaths annually, CRC is ranked the third most common cancer and the fourth most common cause of mortality globally.[5]

In Malaysia, this disease is the second most predominant cancer after breast cancer,[6] whereby, colorectal cancer (CRC) is the commonest cancer among men and the second most common cancer among women.[7, 1] In view of its high incidence, mortality and morbidity rates, and the high socioeconomic burden associated with CRC, it has become one of the paramount and challenging public health problems.[8]

Primary prevention of CRC which based principally on the adoption of healthy lifestyle measures including alterations in dietary habits has not been proven effective, and hence CRC screening turns to be important in improving prognosis and reducing mortality by the detection of cancer at its early stages.[9] One of the main reasons for the high mortality is the high proportion of advanced stage at presentation. Most of the patients are usually symptomatic on presentation.[10] Data from University of Malaya Medical

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Centre (UMMC) showed that 15% of patients presented with Dukes C and 39% with Dukes D disease respectively.[11]

Population-based screening in Malaysia continues to be a challenge, in view of cost and limited availability of colonoscopic skills and facilities. For example, the colonoscopy waiting list for asymptomatic patients in UMMC is six months to a year, causing a delay in diagnosis and management of those in the asymptomatic stages of colorectal carcinoma.[10] Current recommended screening-tools in an average-risk population include yearly faecal-occult blood test (FOBT), five-yearly flexible sigmoidoscopy and ten-yearly colonoscopy.[11] The widely-accepted screening methods currently include fecal occult blood test (FOBT), sigmoidoscopy and colonoscopy.[8] According to the World Gastroenterology Organisation,[13] although these techniques are cost-effective apart from requiring different amounts of resources in terms of financial, professional, facilities and patient effort, they also differ in what stage of the disease detection is possible.

Colonoscopy may be better at detecting pre-malignant conditions which offer CRC prevention. Notwithstanding its reliability, colonoscopy is not practicable in a developing country like Malaysia, being expensive and qualified manpower dependent.[7] FOBT is relatively cheaper and more practical for population screening.[7] Immunochemical faecal occult blood test (iFOBT) is known to be a newer, simpler, more sensitive, less expensive and non-invasive approach to CRC screening available.[2, 3] The most prominent advantage is that iFOBT makes quality control possible. It holds considerable promise in diagnostic performance over the traditional guaiac-fecal occult blood test (g-FOBT). Furthermore, evidence suggests that iFOBT, using one or two samples of faeces, has better clinical sensitivity than g-FOBT does.[14] It detects the presence of haemoglobin, a protein found in blood, which exhibits improved sensitivity and specificity that are higher among those of FOBTs. It also involves no dietary restriction because iFOBT is specific for human haemoglobin, resulting in fewer abnormalities due to interfering substances.[14] Using this level as the selection criterion for colonoscopic screening should therefore decrease the number of unnecessary colonoscopies while maintaining cancer detection rates.

Despite widespread of iFOBT usage, less is understood about the application of iFOBT for CRC detection in Perak, Malaysia. The prevalence of colorectal cancer screening using faecal occult blood tests (FOBT) in the last 12 months in Malaysia was 10.8% (95% CI: 9.47, 12.39); latest National Health Morbidity Survey (NHMS) 2019.[15] The prevalence was highest among adults in the age group of 65 to 69-year-old and retirees. Hence, the present study aims to investigate the use of iFOBT in detecting CRC in a primary care setting in Perak, in order to obtain a more detailed review on iFOBT and its clinical significance towards CRC.

OBJECTIVES

General Objective:

- To describe the characteristics of Colorectal Cancer Screening in Perak, Malaysia

Specific Objectives:

- To describe the socio-demographic features of patients screened for CRC
- To determine the prevalence of positive iFOBT tests among patients screened for CRC
- To assess the association between positive iFOBT tests and sociodemographic characteristics
- To assess the association between positive iFOBT tests and colonoscopic findings of detecting colorectal carcinoma

METHODOLOGY

This was a cross-sectional study. It involved a secondary data review of all patients screened for Colorectal Cancer (CRC) using iFOBT in all government primary health care centres in Perak (95 clinics) from 1st January 2019 until 31st December 2019. Data from all patients who had undergone iFOBT test during the study period were retrieved from an existing Non-communicable Disease Returns database from Perak State Health Department.

The sample size calculation was done for single proportion formula. A total of 412 patients was required to achieve 3% precision in estimating the prevalence of CRC screening using faecal occult blood tests (FOBT) in Malaysia which was 10.8% [15] using Sample Size Calculator for Prevalence Studies, Naing et.al., 2006. However, since universal sampling was applied, all screened cases for one year period were included in this study which was 819.

Permission was obtained from Perak State Health Department to get and use the data of all screened CRC cases reported to them. All data on patients who have undergone iFOBT test from 1st January 2019 to 31st December 2019 were retrieved from the Perak State Health Department's laboratory's existing linked database. Detailed information on colonoscopic findings for those who had undergone colonoscopy were obtained from the Perak State NCD Unit's database.

All cases were kept anonymous. Data were obtained with no name or any identification number/info of all the cases for confidentiality. Cases were numbered accordingly. Data such as age, gender, ethnicity, iFOBT result as well as colonoscopy findings (if any) for each patient were extracted into a simple structured questionnaire. Data were then entered into SPSS and data transformation processed according to the analysis for the objectives. Data analysis was done using SPSS version 25.0. Summary descriptive statistics using frequency and percentage for categorical variables and mean (standard deviation) was analysed for numerical variables. Chi-square test was applied to find out association between

variables. P value less than 0.05 was taken as statistically significant.

There was no risk to the participants as it was a retrospective study. This study did not present any direct benefit to the participants; however, the study did provide a better understanding of the condition studied. The researchers registered this study with the National Medical Research Register (NMRR) and obtained an ethical approval from Malaysian Research Ethical Committee (MREC) before proceeding with the study.

The researchers dealt with all data in a highly confidential manner. No participants' information was divulged in the form of writing, printing, publication and presentation. This study also complied with the ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline. The investigators declared they have no conflict of interest. Director General of Health of Malaysia's approval was obtained prior to publishing this study findings.

RESULTS

In total, 819 participants have been recruited in this study. The mean age was 62.64 (±7.37) years old with minimum and maximum age of the participant was 41 and 85 years old, respectively. Slightly more than half of the respondents were females, 50.7% and males were 49.3%. Majority of respondents were Malays, 57.4%, followed by Chinese, 30.8% and Indians, 10.6% respectively. Majority of the iFOBT tests were done in urban government health clinics (67.8%) (Table 1).

Table 1: Demographics characteristics of all respondents (n=819)

Variable	
Scale variable	**Mean (SD)**
Age	62.64 (±7.37)
Categorical variables	**n (%)**
Gender	
Male	404 (49.3%)
Female	415 (50.7%)
Ethnicity	
Malay	470 (57.4%)
Chinese	252 (30.8%)
Indian	87 (10.6%)
Others	10 (1.2%)
Government Health Clinics	
Urban	555 (67.8%)
Rural	264 (32.2%)

Out of 819 respondents, 3.1% (n=25) of them obtained positive iFOBT results and 96.9% (n=794) obtained negative results, whereby most of them were Malays (1.7%), females (1.6%) with age <65 years old (1.8%) (Figure 1).

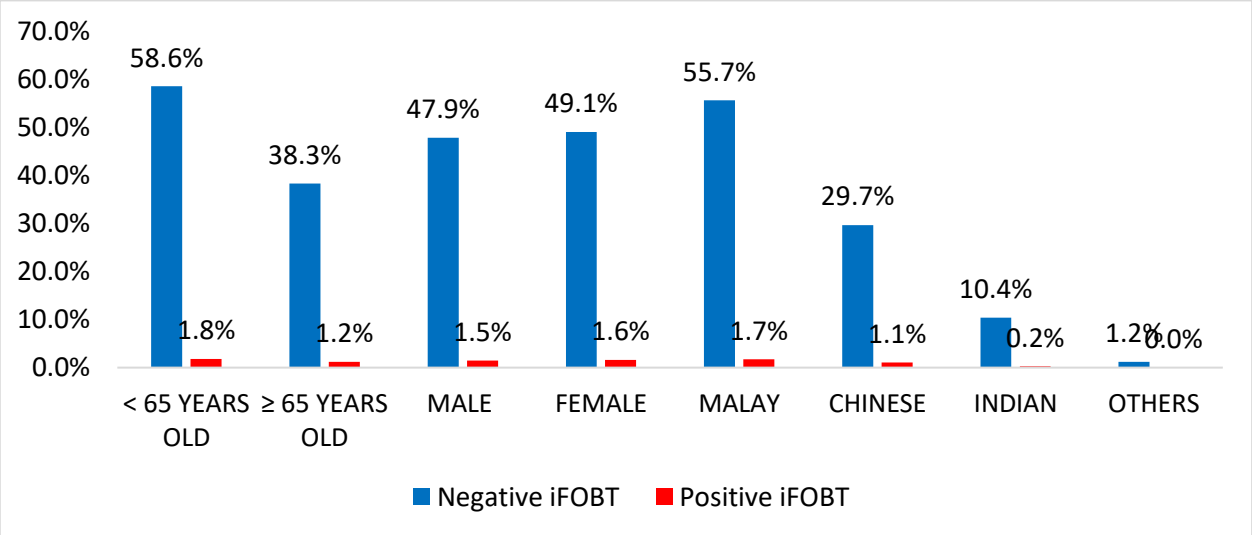

Figure 1: iFOBT test result according to demographic characteristics.

For further analysis on the measurement of significant association, the age parameter was subdivided into 2 categories according to the standard definition of elderly people. Chi Square and Fisher Exact test results revealed no significant association between age, gender, and ethnicity of respondents with iFOBT result. (Table 2).

Table 2: Measures of association between demographic characteristics and iFOBT result.

Variables	iFOBT result n (%)		χ^2	p-value
	Negative	Positive		
Age				
< 65 years old	480 (60.5%)	15 (60.0%)	0.002	0.964
≥ 65 yers old	314 (39.5%)	10 (40.0%)		
Gender				
Male	392 (49.4%)	12 (48.0%)	0.018	0.893
Female	402 (50.6%)	13 (52.0%)		
Ethnicity				
Malay	456 (57.4%)	14 (56.0%)	-	0.876*
Chinese	243 (30.6%)	9 (36.0%)		
Indian	85 (10.7%)	2 (8.0%)		
Others	10 (1.3%)	0		

χ^2 Chi-Square Test, * Fisher Exact Test

Among all the positive iFOBT patients (25), 20 (80%) underwent colonoscopy while only 5 (20%) refused colonoscopy. Among all those who underwent colonoscopy (20), 15 (75%) had normal findings, however, 5 (25%) had abnormal findings which included, 3 with benign lesions (2 with tubular adenoma and 1 with benign polyp), 1 with haemorrhoid and 1 with adenocarcinoma.

Among those who tested positive iFOBT, only 4 of them had pre-cancerous / cancerous lesion findings on colonoscopy. Three of them were aged ≥ 65 years old, 1 was below 65 years old, 2 were males, 2 were females, 3 were Chinese and 1 was Indian.

Table 3: Measures of association between demographic characteristics and colonoscopic findings (pre-cancerous and cancerous lesions)

Variables	Colonoscopic Findings n (%)		p-value*
	Normal/non-cancerous lesions	Pre/cancerous lesions	
Age			
< 65 years old	11 (68.8%)	1 (25.0%)	0.255
≥ 65 years old	5 (31.2%)	3 (75.0%)	
Gender			
Male	7 (43.8%)	2 (50.0%)	1.000
Female	9 (56.2%)	2 (50.0%)	
Ethnicity			
Malay	11 (68.8%)	0 (0.0%)	
Chinese	4 (25.0%)	3(75.0%)	0.037
Indian	1 (6.3%)	1(25.0%)	

* Fisher Exact Test

Analysis of association between the positive iFOBT results, socio demographic characteristics and colonoscopic findings revealed no significant association between age and gender with colonoscopic findings (Table 3). There was significant association between ethnicity and colonoscopic findings (p=0.037), however, only 4 respondents tested positive to iFOBT test

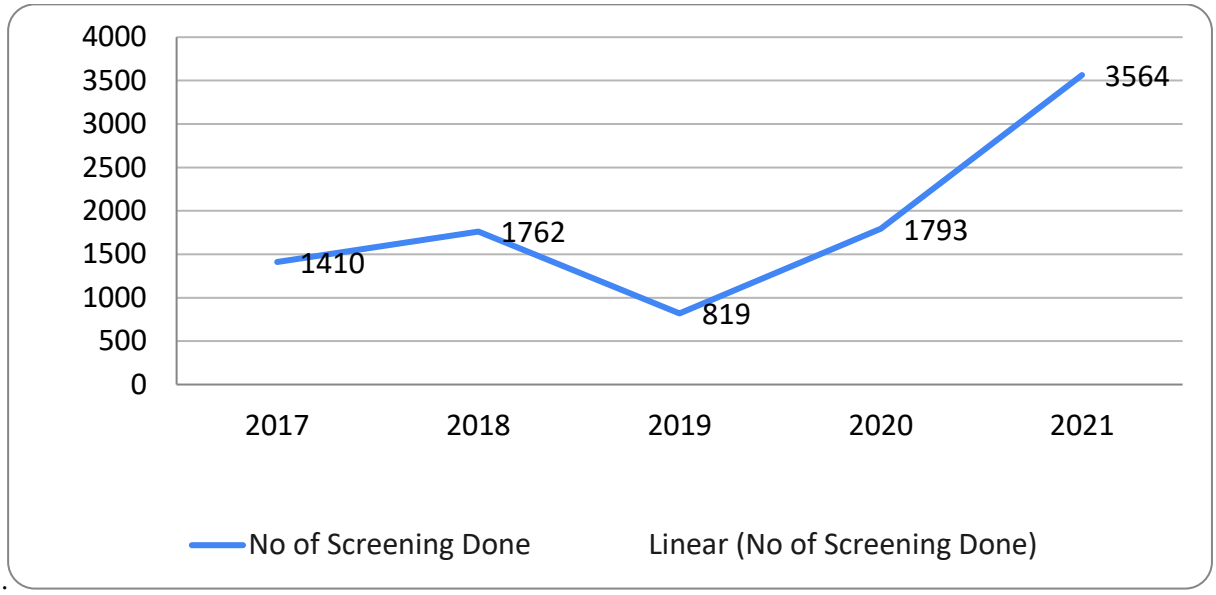

Figure 2: Trend of iFOBT test kits availability for screening of colorectal cancer by the years in Perak

The number of iFOBT test kits available in the year 2019 was the least as compared to the previous as well as the following years; only 819 kits were distributed to Perak from Ministry of Health (MOH), Malaysia. (Figure 2).

DISCUSSION

According to the Malaysia Cancer Registry Report 2012 - 2016, colorectal cancer (CRC) was the most prevalent cancer among males (14.8%) and second common among females (11.1%).[1] Evidence exists that reductions in CRC mortality can be achieved through the detection and treatment of early-stage CRCs. In Malaysia, the CRC screening program was implemented using the WHO stepwise approach in 2014. The target group is asymptomatic males and females aged 50 to 75 years old.[1]

The screening method is using the immunochemical Faecal Occult Blood Test (iFOBT), followed by colonoscopy for those who were found to be positive for iFOBT. Colonoscopy is the gold standard for colorectal cancer diagnosis. The objective of the colorectal screening programme in Malaysia is to detect the pre-cancerous lesion and to detect cancer at the earliest stage possible.

Our study conducted in Perak in 2019, had a total of 819 respondents screened using the iFOBT test. Majority of the iFOBT tests were done in urban government health clinics (67.8%), whereby Kinta (19.2%) and Hilir Perak (19.0%) districts were the highest. Only 25 respondents (3.1%) tested positive which was very low. This is however similar to the findings obtained from another study conducted in Kedah, Malaysia, in 2016, whereby the prevalence obtained was 4.8% in the first round and 3.7% in the second round respectively.[16] Our findings are lower compared to to iFOBT positivity rate (18.8%) in Tokyo[17] however, higher than in Scotland and England.[18, 19] Out of these 25 respondents, 20 respondents (80%) underwent colonoscopy. Even though the number of respondents who underwent colonoscopy was small, the uptake of colonoscopy in this study is much higher than the study done in Kedah which was only 68.1%. Out of 20 respondents who underwent colonoscopy, only 4 respondents (20%) had pre-cancerous (tubular adenoma and polyp) as well as colorectal cancer (sigmoid adenocarcinoma) detected, which was much lower than the study done in Kedah, which was 53.1%.

From this study, the prevalence of colorectal cancer found using iFOBT screening and subsequently referring for colonoscopy was only 1 out of 819 respondents (0.12%,) which was very low. When compared to the National Health Morbidity Survey (NHMS) 2019, in total, 4,351 respondents aged 50 years and above underwent iFOBT testing and the prevalence of colorectal cancer screening using faecal occult blood tests (FOBT) in the last 12 months was 10.8% (95% CI: 9.47, 12.39).[15] The number of respondents in this study in the year 2019 was very much lower than the total numbers screened in NHMS 2019, which could have led to the very low prevalence rate of colorectal cancer obtained in Perak.

In 2019, Perak had lesser iFOBT kits distributed by MOH to be used for screening of CRC, hence, the total respondents screened were low. (Figure 5) It was found that MOH Malaysia had a nationwide problem of obtaining a tender to purchase the iFOBT kits in 2019 and kits which were supposed to be received by all states in early of the year was only obtained in September 2019. The number of iFOBT test kits have increased by 2-fold in the year 2020 and to 4-fold in the year 2021. This would enable a larger percentage of population to be screened for early-stage CRC and to be treated early. Nevertheless, this showed that the prevalence of colorectal cancer screening using the faecal occult blood test was still low nationwide.

This study did not reveal any significant association between age, gender, and ethnicity of respondents with iFOBT result. Analysis of association between the positive iFOBT results, socio demographic characteristics and colonoscopic findings also did not reveal any significant association between age and gender with colonoscopic findings. Although there was significant association found between ethnicity and colonoscopic findings, it however, does not reflect any overall prediction as the number of respondents who tested positive to iFOBT test was too small and the number of respondents who underwent colonoscopy was even smaller. This study findings were similar to the study done in Kedah in 2016, whereby there was also no sociodemographic characteristics associated with positive iFOBT results. The reason could be because of the small sample size, similarly as reported in the study done in Kedah in 2016. However, when compared to the NHMS 2019, the prevalence of colorectal cancer was highest among adults in the age group of 65 to 69-year-old and retirees.

The strength of this study is that universal sampling method was used, even though the sample size was rather small, whereby it exhibits no selection bias. However, our limitations were the nature of the study being retrospective, hence, data such as reasons on why some patients refused to be referred for colonoscopy, as well as other sociodemographic data such as lifestyle of respondents which includes physical activity, dietary history, smoking and alcohol addiction could not be explored further.

CONCLUSION

In conclusion, colorectal cancer screening is a crucial cancer screening program in our effort to reduce all-cause mortality by colorectal cancer. The detection rate for neoplasia and carcinoma is still rather suboptimal using iFOBT test kits most probably due to the low numbers screened. Further strengthening of the program is very much needed to achieve a more favourable outcome. Awareness on acceptance to do iFOBT test in the community can be reinforced by increasing heath care education. Our study team would like to propose for future prospective study with larger sample size to obtain a higher prevalence rate. Future qualitative study to explore further on reasons for early colonoscopy refusal for positive iFOBT patients as well as acceptance do to iFOBT tests would also be beneficial. This would give a better understanding on patients' health seeking behavior which could enable us to prepare and formulate a more structured and individualized counseling method when dealing with patients tested positive for iFOBT who refuse referral for colonoscopy.

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AUTHOR CONTRIBUTIONS:

All 5 authors have contributed significantly in conducting this study, analyzing data and discussing the results obtained.

ETHICAL APPROVAL

This study was approved by Medical Research & Ethics Committee, Ministry of Health Malaysia NMRR-20-2403-56985 (IIR).

CONFLICT OF INTEREST

None of the authors have any conflict of interest in this study.

FUNDING

We did not receive any finding to conduct this research.

DATA SHARING PLAN

Raw data uploaded in publicly available databases can be shared and available upon request.

HOW DOES THIS PAPER MAKE A DIFFERENCE IN GENERAL PRACTICE?

- Colorectal cancer screening is a crucial cancer screening to reduce all-cause mortality by colorectal cancer.
- This study obtained a detailed review on iFOBT and its clinical significance towards CRC in Perak.
- It described the various socio-demographic features of patients screened for CRC and its associations, in Perak.
- It has shown that the detection rate for carcinoma is still rather suboptimal using iFOBT test kits, probably due to the low numbers screened.
- Future qualitative study exploring reasons for early colonoscopy refusal for positive iFOBT patients as well as acceptance do to iFOBT tests would be beneficial.

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