Original Research Article

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Prevalence of colorectal malignant and pre-malignant diseases in faecal immunochemical test positive individuals: an observational study

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ABSTRACT

Background: Colorectal cancer (CRC) is a challenging clinical entity worldwide. Adenomatous polyps are considered precursors to cancer. For early detection of polyps or ulcers, different screening investigations like colonoscopy, faecal immunochemical test (FIT), gFOBT, CT colonography etc. are used. Despite colonoscopy is being a highly accurate and gold standard therapeutic, it is not easily available in remote areas. The FIT, one of several tests available for CRC screening, is currently used in many countries and well accepted to all patients. **Methods:** To find out the prevalence of colorectal malignant and pre-malignant diseases in FIT positive individuals. This prospective cross-sectional observational study was done in the department of colorectal surgery, Bangabandhu Sheikh Mujib medical university (BSMMU), Dhaka. A total 140 patients were selected according to the inclusion and exclusion criteria. FIT was done who matched. Colonoscopy was done in the FIT positive individuals.

Results: The study patients were aged \geq 45 years, with a mean age of 51.73 ± 7.97 years. The most common clinical finding was abdominal pain (n=117), followed mucous discharge (n=56) and changes in bowel habit (n=47). Colonoscopy revealed that 50% of the patients had polyps, 10.71% had nonspecific ulcers, 2.86% had growths, and 12.14% had haemorrhoids. Histopathology showed that 61.43% of the polyps were hyperplastic polyps, and 63.16% of the ulcers were non-specific colitis. Most of the patients had single polyps in colonoscopy. Sensitivity, specificity and PPV of FIT is 85.7%, 97.5% and 66.4% respectively.

Conclusions: The consistent evidence linking FIT positivity to the presence of colorectal malignant and premalignant diseases reinforces its efficacy as a frontline screening tool.

Keywords: Colorectal cancer, Faecal immunochemical test, Guaiac faecal occult blood test

INTRODUCTION

Colorectal cancer (CRC) is the third leading cause of cancer death for both men and women, with an estimated 52 980 persons in the US projected to die of CRC in 2021. CRC is most frequently diagnosed among persons

aged 65 to 74 years.² It is estimated that 10.5% of new CRC cases occur in persons younger than 50 years.³ Incidence of CRC (specifically adenocarcinoma) in adults aged 40 to 49 years has increased by almost 15% from 2000-2002 to 2014-2016.⁴ In 2016, 25.6% of eligible adults in the US had never been screened for CRC and in 2018, 31.2% were not up to date with screening.⁵

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Many countries have introduced a screening program for CRC in recent years. Different screening modalities are suitable for that purpose. Opportunistic screening programs most often use colonoscopy for primary screening, while organized.⁶

The FIT, one of several tests available for CRC screening, is currently used in many countries.⁷

Population-based programs mostly prefer FITing.⁸ Colonoscopy has better test characteristics compared with FIT when applied for 1-time screening, yet is invasive, burdensome, and costly. FIT is noninvasive, non-burdensome, and less costly, but has higher test sensitivity.⁹⁻¹¹ For optimal program sensitivity and preventive effect, FIT should be repeated regularly. FIT has been shown to be effective in detecting CRC at low cutoffs or short screening intervals.¹² Modeling studies suggested that by repeating FIT annually, with an assumed test sensitivity of 73.8% for CRC, the long-term preventive effect would be similar to colonoscopy screening.

In a resource-limited country, a screening test such as FIT may increase the level of participation in CRC screening. The prevalence of positive FITs is yet to be determined in our study center. This study aims to determine the percentage of patients with positive FIT results having CRC and premalignant stage and the feasibility of FIT screening in the study area.

METHODS

A cross-sectional observational study was employed to assess the effectiveness of the lifestyle intervention program in BSMMU in between July 2022 to June 2023. All patients over 45 years presented in OPD colorectal surgery, BSMMU were included. Patients with hematochezia or severe comorbidity were excluded. Patients were advised for FIT. No dietary restriction was made. Patients were given a test card to collect stool sample. Test card detects antibodies to the human protein globin portion of hemoglobin found in red blood cells. A total of 5760 patients were recruited. Out of them 140 patients were found FIT positive underwent colonoscopy. Ethical clearance was taken from IRB of university and data analyzed with SPSS. Sample size was calculated.

RESULTS

Table 1 shows the distribution of the study patients by age. It was observed that most patients belonged to 48 (34.29%) patients belonged to age 51-55 years followed by 36 (25.71%) in the age group of 46-50. The mean age was 51.73±7.97 years.

Table 2 shows the distribution of the study patients by clinical findings. It was observed that majority 117 patients had abdominal pain followed by 56 had mucous

discharge, 47 had changes in bowel habit, 13 had weight loss and 9 had complain of loss of appetite.

Table 1: Distribution of the study patients by age, (n=140).

Age (in years)	N	Percentage (%)
46-50	36	25.71
51-55	48	34.29
56-60	34	24.29
61-65	12	8.57
66-70	9	6.43
≥70	1	0.71
Mean±SD	51.73±7.97	1
Range (min and max)	46-70	

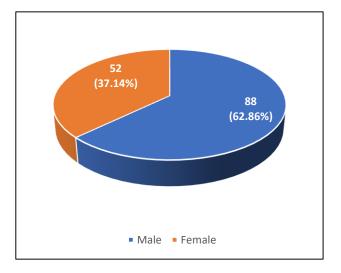


Figure 1: Distribution of the study patients by gender, (n=140).

Table 2: Distribution of the study patients by clinical symptoms.

Clinical symptoms	N
Changes in bowel habit	47
Mucous discharge	56
Abdominal pain	117
Loss of appetite	9
Weight loss	13

Table 3 shows the distribution of FIT-positive and FIT-negative results among 5760 patients. It was observed that 140 (2.43%) patients were FIT-positive, while 5620 (97.57%) patients were FIT-negative.

Table 3: Distribution of FIT positive and FIT negative patients, (n=5760).

FIT	Number of patients	Percentage (%)
FIT positive	140	2.43
FIT negative	5620	97.57

Table 4 shows the distribution of the study patients by colonoscopic findings. It was observed that 14.29% patients showed normal finding. 70 (50.00%) patients had polyps. The 15 (10.71%) patients had nonspecific ulcer, 4 (2.86%) patients had growth and 17 (12.14%) had haemorrhoid.

Table 5 shows the distribution of benign and malignant lesions identified in the study. Among the 70 polyps, the majority were hyperplastic polyps 43 (61.43%) cases, while tubular adenomas with low-grade dysplasia accounted for 11 (15.71%) cases. Other polyp types included adenomas with high-grade dysplasia 7 (10.00%) cases and adenomas with villous histology 4 (5.71%) cases, with 2 (2.86%) cases classified as malignant polyps. Ulcers, comprising 19 cases, were predominantly non-specific colitis 12 (63.16%) cases. Other ulcer types included ulcerative colitis 1 case, (5.26%), Crohn's disease, and tuberculosis 3 (15.79%) cases. No malignant ulcers were observed. For growths, all 4 cases were

classified as adenocarcinomas, representing 100% of the growth lesions.

Table 4: Colonoscopic findings of study patients, (n=140).

Colonoscopic findings	N	Percentage (%)
Polyps	70	50.00
Ulcer		
Ulcerative colitis	1	0.71
Crohn's	3	2.14
Non specific	15	10.71
Growth	4	2.86
Haemorrhoid	17	12.14
Diverticulosis	3	2.14
Fissure	4	2.86
Fistula	3	2.14
Normal	20	14.29

Table 5: Distribution of study patients by histopathological findings, (n=93).

Lesion type	Benign	N	Percentage (%)	Malignant	N	Percentage (%)
	Hyperplastic polyp	43	61.43	Adenoma with villous histology	4	5.71
Polyp, (n=70)	Tubular adenoma with LGD	11	15.71	3 or more adenoma	3	4.29
				Adenoma with HGD	7	10
				Malignant polyp	2	2.86
	Non-specific colitis	12	63.16	Malignant	0	0
Ulcer,	Ulcerative colitis	1	5.26			
(n=19)	Crohn's	3	15.79			
	TB	3	15.79			
Growth,				Adeno carcinoma	4	100
(n=4)				Aueno caremoma	4	100

Table 6: Clinical tests of FIT.

Metric	Value (%)
Sensitivity	21.80
Specificity	97.80
Positive predictive value (PPV)	50.00
Negative predictive value (NPV)	91.76

This table shows the clinical performance of the FIT based on a sample of 140 individuals. The test demonstrated a sensitivity of 21.8%, specificity of 94.8%, PPV of 50%, and a NPV of 94.76%.

Table 7: Distribution of the study patients by number of polyps in colonoscopy, (n=70).

Number of polyps in colonoscopy	N	Percentage (%)
Single	51	72.86
Double	16	22.86
More than two	3	4.29

Table 7 shows the distribution of the study patients by number of polyps in colonoscopy. It was observed that more than two third 42 (72.4%) patients had single polyp in colonoscopy had single followed by 13 (22.4%) double and 3 (5.2%) more than two.

DISCUSSION

In this study, it was observed that most patients belonged to 48 (34.29%) patients belonged to age 51-55 years followed by 36 (25.71%) in the age group of 46-50. The mean age was 51.73±7.97 years with ranged from 46 to 70 years. The mean age was 51.73±7.97 years. In this study, 88 (62.86%) were male and 52 (37.14%) were female. In another study, the mean age for men was 60.8 years (median of 61 years, with 25% being above 70 years), while for women it was 61.1 years (median of 63 years, with 25% being above 68 years). This was comparable to our study and there was no significant difference in age between the genders. They also reported that male gender was a factor for having any adenoma and CRC, which occurred in 50 patients. The age range of the patients in this study was 15 to 80 years, with the

most common age group being 35-44 years (28%), followed by 25-34 years (24%), and the mean±SD was 40.9±16.06 years. ¹³ The age group of 35-44 years old was reported to have the highest frequency of CRC detection (28%) in a study conducted in Bangladesh. I chose a smaller age range group for my study because of this. ¹⁴

In this study, among 5760 patients it was observed that 140 (2.43%) patients were FIT positive, while 5620 (97.57%) patients were FIT negative.

In current study, the distribution of the study patients by clinical findings showed that majority (117) patients had abdominal pain followed by 56 had mucous discharge, 47 had changes in bowel habit. 13 had weight loss and 9 had complain of loss of appetite (Table 2). This study is similar to the study by Atkin. 15

In colonoscopy, commonest diagnosed cases were polyps of various types. More than 70 (50.00%) patients had polyps. Normal findings also revealed in 14.29% cases, followed by ulcer in 19 (13.56%) and haemorrhoid in 12.14% cases.

In this study, the distribution of lesions identified through FIT screening reveals significant insights into the prevalence and type of findings. Among the 70 polyps, the predominant lesion was hyperplastic polyps, accounting for 61.43% of cases, indicating their common occurrence in this cohort. Tubular adenomas with lowgrade dysplasia were found in 15.71% of cases, while adenomas with high-grade dysplasia and those with villous histology constituted 10.00% and 5.71% of the polyps, respectively. Notably, 2.86% of polyps were classified as malignant. The analysis of ulcers, which included 19 cases, showed that non-specific colitis was the most frequent type, present in 63.16% of cases. Other ulcer types, such as ulcerative colitis, Crohn's disease, and tuberculosis, were less common, with no malignant ulcers observed. The findings were further underscored by the observation that all 4 growths were adenocarcinomas, highlighting a 100% rate of malignancy among growth lesions. This distribution underscores the utility of FIT in identifying various lesion types, emphasizing its role in detecting both benign and malignant conditions effectively.

In a similar study, three or more polyps in 2.7% cases were found. They also found two or more advanced adenomas in 11%. In this study about 80.8% patients showed single polyp. ¹⁶ In another study by Wilen et al 20% single polyps, followed by 5.2% double and 2.9% more than three polyps were also found. ¹⁶

In this study, the FIT exhibited a high specificity of 94.8% and a sensitivity of 21.8%. This high specificity demonstrates the test's strong ability to accurately identify individuals without colorectal disease, effectively minimizing false positives. The sensitivity of 21.8% suggests that while the FIT is less effective at detecting

all cases of disease, it is still a valuable tool for screening. These findings align with those of another study, which reported similar results with a sensitivity of 21.8% and specificity of 97.8%, reinforcing the reliability of FIT in ruling out disease.¹⁷ Overall, the high specificity and substantial negative predictive value of the FIT emphasize its effectiveness in reducing unnecessary follow-up procedures and providing accurate reassurance for individuals who test negative.

In current study, regarding the distribution of the study patients by number of polyps in colonoscopy, it was observed that more than two third 51 (72.86%) patients had single polyp in colonoscopy, followed by 16 (22.86%) double and 3 (4.29%) more than two.

In a similar study, 2.7% of cases had three or more polyps. Additionally, 11% of them had two or more advanced adenomas. About 80.8% of the patients in this study showed a single polyp.¹⁶

Rigorous participant selection criteria based on age, gender, and other relevant factors ensure the studies provide robust and representative data for analysis. The results across these recent observational studies consistently reveal a noteworthy prevalence of colorectal malignant and pre-malignant diseases in FIT positive individuals.¹⁸ A large-scale study uncovered a significant association between FIT positivity and the presence of advanced adenomas and early-stage CRC. 19 This was further corroborated by a parallel study conducted by strengthening the evidence that FIT positivity is indicative of a higher risk of colorectal lesions. 20-22 Further examination of prevalence rates among FIT positive individuals exposed intriguing patterns. Age, a well-established risk factor for CRC, surfaced as a significant variable. Individuals over the age of 50 exhibited higher rates of FIT positivity and, consequently, a heightened risk of colorectal lesions. differences also emerged, with demonstrating higher FIT positivity rates than women.²³ Understanding these demographic variations provides crucial insights for tailoring screening approaches based on individual risk profiles. The interpretation of these study findings necessitates a nuanced understanding of the strengths and limitations inherent in observational research.

While FIT offers high sensitivity and specificity, it is not infallible. False positives and false negatives can occur, prompting the need for additional diagnostic evaluations. The observational nature of these studies introduces potential biases, including confounding variables and selection biases. However, the consistency of findings across multiple studies strengthens the case for an association between FIT positivity and colorectal lesions. The discussion extends beyond statistical associations to the clinical relevance of FIT positivity. Detection of colorectal lesions in FIT positive individuals

raises the question of how promptly and effectively these lesions are managed.

The implications of these findings extend to the realm of public health policies and CRC screening programs.²⁷ Tailoring screening strategies based on demographic factors, as highlighted by the age and gender disparities in FIT positivity, could optimize the efficacy of screening initiatives. Moreover, public health campaigns targeting high-risk populations, such as older individuals and men, may play a pivotal role in encouraging timely participation in screening programs.²⁸ Integrating FIT into national screening programs has the potential to significantly impact CRC-related morbidity and mortality.²⁹ However, the success of such programs hinges not only on the efficacy of the screening tool but also on addressing barriers to screening participation. Educational campaigns, accessibility to screening facilities, and ongoing surveillance are integral components of a comprehensive public health approach to CRC prevention.30

These findings affirm the efficacy of FIT as a valuable screening tool, emphasizing its crucial role in early detection and prevention. While acknowledging the limitations inherent in observational research, the cumulative evidence supports the integration of FIT into comprehensive CRC screening programs. As the landscape of CRC screening evolves, continuous refinement of screening strategies is essential.³¹ This involves addressing demographic variations in FIT positivity, enhancing public awareness, and optimizing the entire screening-to-intervention continuum. Ongoing research, collaboration, and innovation will be pivotal in advancing CRC screening and, ultimately, in reducing the global burden of this disease.³²

CRC remains a formidable global health challenge, necessitating effective screening tools for early detection. Among these, the FIT has gained prominence due to its simplicity and accuracy.³³ This discussion delves into recent observational studies, exploring the prevalence of colorectal malignant and pre-malignant diseases in FIT positive individuals and its implications for screening strategies.

CRC often originates from pre-malignant lesions such as adenomas and polyps, making early detection crucial. These lesions, if left untreated, can progress to malignancy, underlining the importance of effective screening methods. Identifying individuals with premalignant conditions allows for timely intervention, potentially preventing the development of full-blown CRC.³⁴

Recent studies consistently reveal a significant prevalence of colorectal malignant and pre-malignant diseases in FIT positive individuals. In a large-scale study demonstrated a clear association between FIT positivity and the presence of advanced adenomas and early-stage

CRC. These findings were corroborated reinforcing the evidence that FIT positivity indicates a higher risk of colorectal lesions. 35,36

Further analysis of prevalence rates among FIT positive individuals unveiled intriguing patterns. Age emerged as a significant factor, with individuals over 50 exhibiting higher FIT positivity rates and an elevated risk of colorectal lesions. Gender differences were also notable, with men showing higher FIT positivity rates than women. Understanding these demographic variations provides crucial insights for tailoring screening approaches based on individual risk profiles.

Interpreting these findings requires acknowledging the strengths and limitations inherent in observational research. While FIT offers high sensitivity and specificity, it is not infallible. False positives and negatives can occur, necessitating additional diagnostic evaluations.³⁷ The consistency of findings across studies strengthens the case for an association between FIT positivity and colorectal lesions.

Implications extend to public health policies and CRC screening programs. Tailoring screening strategies based on demographic factors, as highlighted by age and gender disparities in FIT positivity, could optimize screening efficacy. Public health campaigns targeting high-risk populations, such as older individuals and men, may encourage timely participation in screening programs.

Limitations

FIT may yield false-positive results due to factors such as gastrointestinal bleeding from non-colorectal sources or dietary influences. FIT may yield false-negative results due to the size and location of colorectal lesions, patient-specific factors, or assay variability.

CONCLUSION

In conclusion, the exploration of recent observational studies underscores the pivotal role of the FIT in CRC screening. The consistent evidence linking FIT positivity to the presence of colorectal malignant and pre-malignant diseases reinforces its efficacy as a frontline screening tool. These findings carry significant implications for public health strategies, emphasizing the importance of tailored screening approaches based on demographic factors. Demographic variations in FIT positivity, notably age and gender disparities, highlight the need for personalized screening strategies. Targeted public health campaigns for high-risk populations can foster awareness and encourage timely participation in screening programs. While acknowledging the limitations inherent in observational research, including potential biases and false results, the cumulative evidence supports the integration of FIT into comprehensive CRC screening initiatives. As we navigate the future of CRC screening, continued research, innovation, and collaboration among healthcare professionals, researchers, and policymakers are essential. Addressing barriers to participation and ensuring ongoing surveillance will be crucial for maximizing the impact of FIT on early detection and prevention. Ultimately, the journey ahead involves refining strategies, promoting accessibility, and maintaining a collective commitment to reducing the global burden of CRC through effective and targeted screening efforts.

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Institutional Ethics Committee

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