

Implementing Faecal Immunochemical Testing in Primary Care

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Abstract

Aims

The incidence of colorectal cancer (CRC) has increased globally, in particular patients under the age of fifty. This is a pilot study of a faecal immunochemical testing (FIT) service in primary care. The aim was to trial a FIT service for asymptomatic patients.

Methods

We offered FIT kits to asymptomatic patients, aged between 40-75 years old during routine consultations. The number of FITs performed and the outcomes were reviewed. A cut-off of $> 10\mu\text{g Hb/g}$ faeces was defined as a positive result.

Results

Overall 180 FIT kits were distributed, 7 duplicate tests were given. Of the 173 patients recruited, 142 (82%) samples were analysed in the lab. A total of 126 (88.7%) samples had a normal result, 8 (5%) were rejected, 31 (17.9%) did not send their sample for analysis. A positive result was found in 8 (5%), of these 6 (75%) underwent colonoscopy. No cancer was identified, 4 (50%) had polyps removed and 2 patients require follow up colonoscopy.

Discussion

This study represents the first successful implementation of a FIT service in primary care in Ireland. There is a significant unmet need in this setting and strong scientific rationale for the use of FIT testing in general practice.

Introduction

Colorectal cancer (CRC) is a public health issue and with an aging population, the incidence is expected to increase significantly. There is evidence also that the incidence of CRC in patients under the age of 50 has increased, this is referred to as young onset colorectal cancer (YO-

CRC)¹⁻³. CRC is the second most common cause of cancer death in Ireland.⁴ The 5-year survival rate for localized disease is 91% and advanced disease is 12%.⁵

BowelScreen is run by the National Screening Service (NSS) in Ireland for CRC; it started in 2012 and uses faecal immunochemical test (FIT). FIT is an antigen-antibody reaction which has specificity to human haemoglobin in the lower digestive tract. At present BowelScreen offers a FIT screening test to those ages 59-69 years old. It is due to expand to include those aged 55-74 age group on a phased basis. The expansion of the service is limited by the capacity of endoscopy services.⁶

In 2016, the screening uptake rate was poor at 41.4%⁵. In Ireland, CRC incidence was higher than average in two areas, Co. Cork, in an area centred on Cork city but extending into the far southwest, and in the north and centre of the country, in a broad band from Dublin heading through the northeast towards Donegal.⁷

FIT has another role for symptomatic patients suspected with CRC. NICE recommend the use of FIT in general practice for patients with suspected colorectal cancer and to guide referral pathways.⁸ As per this NICE guideline, FIT testing for suspected CRC is now a standard practice in primary care in the UK. FIT can help prioritise patients with clinical features of CRC for referral for urgent colonoscopy. The threshold number for this is lower than the screening programmes. The use of FIT helps triage those referred to the hospital and help relieve capacity issues and waiting times.⁹ The evaluation of symptomatic patients can be challenging as the gastro-intestinal symptoms of CRC are often non-specific.¹⁰ Most patients presenting with these symptoms will not have a cancer.¹¹ The use of FIT offers an opportunity to use a test superior in terms of positive predictive value (PPV) for CRC, compared to symptoms alone.¹² In Ireland FIT is not used as a tool in general practice to prioritise referral for colonoscopy in symptomatic patients.

In this study, a FIT service was initiated in a GP practice in Cork. The primary aim was to implement FIT in a primary care setting. Specifically, the FIT service was offered to asymptomatic patients aged 40-75 years. It's important to note that this study was not designed to evaluate diagnostic performance.

Methods

A FIT service was introduced in March 2023 in Salutem Clinic, Ovens, Co Cork. It is a single handed GP practice with a patient population of approx. 4,000. FIT kits were provided free of charge from Eurofins Biomnis. Patients were recruited opportunistically during routine

consultations by the doctors. A FIT kit contains; a green sampling stick, green plastic bag to protect sample from day light, a test request form and a lab-addressed post-paid envelope. Patients were recruited as per the following inclusion and exclusion criteria; Inclusion criteria: 1. 40-75 years of age 2. Asymptomatic. Exclusion criteria: 1. Aged over 75, under 40 2. Pregnant or breastfeeding. 3. Inherited bowel conditions (Familial adenomatous polyposis (FAP) /Hereditary Non-polyposis colorectal cancer (HNPCC)) 4. Symptomatic (abdominal pain, change in bowel habit, unexplained anaemia, weight loss, rectal bleeding, blood on tissue or in stool, abdominal or rectal mass) 5. Those who participated in Bowelscreen programme in last 12 months.

Patients were given a patient information leaflet and also the test instructions. Informed consent was obtained and the signed consent forms were scanned on to the patient's electronic chart. The patients received a copy of their consent for their own records. Each patient was given the FIT kit to take home and perform the test. The sample was then deposited into a post-box by the patient. The sample must be processed in the lab within 10 days of the test being performed.

The samples were posted to Eurofins Biomnis in Dublin. Analysis was performed using a single OC-Sensor Pledia. The laboratory is accredited by the Irish National Accreditation Board(INAB), Reg no. 159MT. The results of the FIT were posted to the practice and scanned on to the patient's electronic chart. The patients were contacted by the doctor and results were explained.

In partnership with the Mercy University Hospital, a patient who had a positive FIT result was referred directly for a colonoscopy. Referrals were sent to a dedicated consultant as part of this pilot study.

Patients were recruited from March 2023 until August 2023. The results and outcomes were reviewed until December 2023. Result's data and patient demographics were obtained from the primary care electronic system SOCRATES. The outcome of the colonoscopy was determined by reviewing clinical notes, endoscopy and histology reports from secondary care correspondents. Outcome measures: 1. Number of requested FITs. 2. FIT results; defined as: positive ($> 10\mu\text{g Hb/g faeces}$), negative ($<10\mu\text{g Hb/g faeces}$) or invalid. 3.Diagnostic investigations after the FIT request; defined as: sigmoidoscopy, colonoscopy or CT-colonography. 4. Diagnoses after the FIT request.

Statistical Analysis was not performed as this was a small sample size.

Results

During the study period a total of 180 FIT kits were distributed. Of these, 7 of which were duplicates as patient's original FIT sample was not processed. The patients who received a second FIT kit did not undertake the second sample.

Of the 173 patient's recruited, 31 (17.9%) did not send their sample for analysis. A total of 142 (82.1%) samples were analysed in the lab. Of these, 8 (4.6%) samples were not processed due to the sample expiring the ten day window, from the time the sample was taken and received in the lab. A total of 126 (88.7%) samples had a normal result and 8 (5%) of FIT results were found to be abnormal (see figure 1 and 2).

The demographics of patients recruited showed an average age of 53 years and an average BMI of 27. A majority of patients were non-smokers 153 (88.4%), smokers 12 (6.9%) and ex-smoker 8 (4.6%). A total of 92 (53%) of males and 81(46.7%) of females were recruited. A summary of the age distribution and sex can be seen in table 1. In the separate age categories, the younger age of 40-49 years made up 72(41.6%) of the total number recruited.

Abnormal Results

With the use of a more sensitive cut off of $>10 \mu\text{g Hb/g}$ our recruitment yielded 8 (6.3%) positive FIT results. The exact figure of $\mu\text{g Hb/g}$ faeces is shown in table 2. It ranged from 10.2-128.2 $\mu\text{g Hb/g}$. The patient's age ranged from 43 to 70 years, male: female was ratio 5:3, 7 non-smokers and 1 ex-smoker.

Of the 8 patients referred, a total of 6 underwent a colonoscopy. One patient was pending a colonoscopy at the study end date. One patient declined to undergo a colonoscopy. No cancer was identified in those who underwent colonoscopy. The endoscopic findings were as follows; polyps identified (n=3), polyp and haemorrhoid (n= 1), haemorrhoids alone (n= 1), normal colonoscopy (n=1). These results are summarised in table 2 . Depending on the histology of the polyp some patients require a repeat colonoscopy in 5 years' time (n = 2).

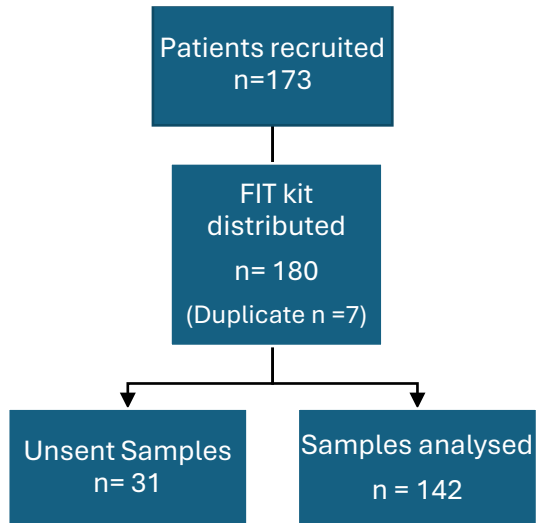


Figure 1: Flow chart of FIT requests.

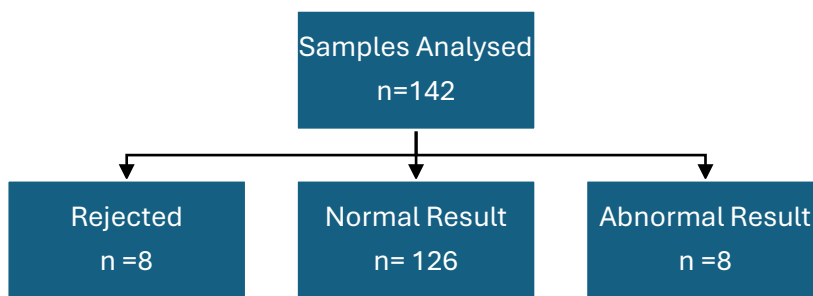


Figure 2: Flow chart of samples analysed.

	40-49 years	50-59 years	≥60 years	Total
n (%)	72 (41.6%)	55(31.7%)	46(26.5%)	173
Male	35	28	29	92
Female	37	27	17	81
Median age	45 years	54 years	66 years	58 years

Table 1: Demographics of patient recruited for faecal immunochemical testing.

Patient	Age	µg Hb/g faeces	Colonoscopy Result	Size	Morphology	Follow up
1	43	41	Polyp	1mm	Tubular adenoma with low grade dysplasia	5 years
2	43	32.8	Haemorrhoids	0	0	No
3	54	10.2	Polyp	2mm	Hyperplastic polyp	No
4	53	128.2	Polyp	5mm,10mm	Sessile serrated polyps, no dysplasia	No
5	62	28	Normal	0	0	No
6	65	78	Pending*	0	0	N/A
7	65	29	Declined	0	0	N/A
8	70	68.4	Polyp & Haemorrhoids	3mm	Tubular adenoma with low grade dysplasia	5 years

*Table 2: Summary of patients with abnormal/ positive FIT result. *Pending colonoscopy at end date of study.*

Discussion

The use of FIT in general practice can serve two purposes: 1) A CRC screening test 2) To prioritizing referrals in symptomatic patients. It's important to understand that the test threshold differs for a screening programme and for symptomatic patients. The patient age profile and cut off values differ across international screening programmes. For example the positivity threshold ranges from 15 $\mu\text{g Hb/g}$ in Norway to 150 $\mu\text{g Hb/g}$ in Wales.⁵ Studies have shown that sensitivity and positive predicted value of a positive FIT are lower in younger patients compared with older patients.¹² A cut-off threshold of 10 $\mu\text{g Hb/g}$ faeces has sensitivity of 87.5% in those < 50 years of age compared with 97.4% in those ≥ 50 years of age.¹²

The bowelscreen programme had a threshold of $\geq 20 \mu\text{g Hb/g}$ initially, but this was revised to $\geq 45 \mu\text{g Hb/g}$ in 2017. This change was made because there was a large number of false positive rates and with the lower threshold more than 8% of the patients were being referred for colonoscopy.⁵ The resources to provide colonoscopy was not available. The Bowelscreen Expert Reference group report discussed a lower threshold being used in the future when endoscopy capacity increases.⁵ The balance needs to be found in choosing a threshold in terms of numbers needed to scope (NNS) to detect one cancer and the numbers of missed cancers(NMC) per 1,000 patients.

Our study highlights the crucial role that GPs play in promoting population-based screening programs and facilitating early cancer detection. Among recipients of the FIT kit, 82% obtained a result, highlighting the success of the service. This reflects patient compliance and acceptability of FIT in primary care. The patient demographics showed overall similar participation by both male and female. The BowelScreen Programme had a screening uptake rate of 41.4%, men are engaging less which is of concern as colon cancer affects men more than women.^{5,7} Studies have shown that GPs who encourage bowel screening participation have improved uptake and compliance.¹³ With support from professional bodies and standardised reporting FIT is appropriate for general practice use.

In this study the younger age category of 40-49years, made up 72 (41.6%) of the total number of recruited patients. This may represent a population cohort who are more health aware and proactive in prevention and detection of cancer. The American Cancer society and the US Multi-Society Task Force on CRC have recommended to begin screening at the age of 45 years old.^{1, 14, 15} It is thought that lifestyle factors such as obesity, antibiotic use, poor physical activity and diet may play a part in early-onset CRC, defined as those under the age of 50.¹ Younger patients present with more advanced disease compared with those over 50

years old.³ This highlights the need to be attentive when young patients present with gastrointestinal symptoms.

Another value of a FIT service, is in the stratification of risk in the referral of symptomatic patients. The Association of Coloproctology of Great Britain & Ireland (ACPGBI) and the British Society of Gastroenterology (BSG) published guidance on the use of FIT in patients with signs or symptoms of suspected colorectal cancer.¹² The joint guideline recommend the use of FIT in primary care to prioritise patients with clinical features of CRC for urgent investigation. The threshold of $\geq 10 \mu\text{g Hb/g}$ of faeces should be used to select patients with symptoms for urgent referral pathway. This is currently not available in Ireland for GPs.

A strength of this study was that FIT was used in every day clinical practice. Although it is important to note time pressures exist for GPs, patients are keen to listen to their own GP with regards health promotion. Overall the time taken to consent a patient, and explain the FIT kit and it's use did not overrun the daily clinics.

This study has limitations. It was a small scale research project conducted in a single GP practice with a well-informed population. This is reflected in the number of non-smoker (88.4%) to smokers 12(6.9%). As the patients' family doctor, we may have intentionally chosen participants whom we believed were more likely to engage, introducing a potential selection bias in this study. Another limitation was the length of time for recruitment; during the summer months many patients were out of their typical routine and practice footfall was lower compared to winter months. Further research to explore strategies to maximise return of FIT kits and conduct a cost analysis of the intervention would be beneficial, these were beyond the scope of this pilot study.

In summary, there exists a significant unmet need in this context, along with strong scientific rationale for implementing FIT testing in general practice. In the future, FIT may be used to triage symptomatic patients for referral to endoscopy. This study is a stepping stone to explore a FIT service for symptomatic patients, where further research on the subject is welcome.

Declarations of Conflicts of Interest:

None declared.

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Abbreviations:

Association of Coloproctology of Great Britain & Ireland (ACPGBI)

British Society of Gastroenterology (BSG)

Colorectal cancer (CRC)

Familial adenomatous polyposis (FAP)

Faecal Immunochemical Test (FIT)

Hereditary Non-polyposis colorectal cancer (HNPCC)

National Institute for Health and Care Excellence (NICE)

National Screening Service (NSS)

Young onset Colorectal Cancer (YO-CRC)

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