


Original research

Prioritisation of lower gastrointestinal endoscopy during the COVID-19 pandemic: outcomes of a novel triage pathway

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ABSTRACT

Objective The 2-week-wait (2ww) referral pathway is used in England to fast-track patients with suspected colorectal cancer (CRC). A two-stage triage pathway was used to prioritise lower gastrointestinal (LGI) endoscopy for suspected CRC during the COVID-19 pandemic.

Method All patients referred for an LGI endoscopy via a 2ww referral pathway between March 2020 and July 2020 were assessed. The first stage triaged patients to high, standard or low risk of CRC based on symptoms and faecal immunochemical test (FIT), and offered CT scans to those at high risk. The second stage, endoscopy prioritisation (EP), incorporated the CT results, FIT and symptoms to triage into four groups, EP1–EP4; with EP1 being the most urgent and EP4 the least. The primary outcome measure was CRC detection.

Results 514 patients were included. The risk of CRC was triaged as high in 190/514 patients (37%), standard in 274/514 patients (53%) and low in 50/514 (10%) patients. 422/514 patients (82%) underwent endoscopy with triage to EP1 in 52/422 (12%), EP2 in 105/422 (25%), EP3 in 210/422 (50%) and EP4 in 55/422 (13%). CRC was detected in 23 patients (5.4%). CRC was significantly more frequent in the EP1 group (23.1%, relative risk (RR)=16.2) and EP2 group (6.7%, RR=4.7) compared with EP3 group (1.4%). All CRC lesions were identified by CT imaging when performed prior to LGI endoscopy.

Conclusion This triage pathway designated 83% of patients with CRC to either EP1 or EP2. During a period of limited endoscopy provision, this pathway effectively prioritises endoscopy for those at greatest risk of CRC.

Key points

What is already known on this topic?

- The COVID-19 pandemic led to a significant reduction in the provision of endoscopy.
- The faecal immunochemical test (FIT) and symptoms predict risk of colorectal cancer (CRC), but prioritisation strategies for endoscopy have not been defined.

What this study adds?

- The majority of 2-week-wait referrals diagnosed with CRC have predictable high-risk features.
- A two-stage triage pathway, which used patient symptoms, FIT results and CT results, effectively prioritised patients for lower gastrointestinal endoscopy.

How might it impact on clinical practice in the foreseeable future?

- During periods of limited endoscopy provision, effective triage allows appropriate prioritisation of resources.
- This two-stage pathway both identified those at highest risk of CRC for further investigation with interim CT and prioritised the majority of CRC to undergo urgent endoscopic examination.

INTRODUCTION

The 2-week-wait (2ww) referral pathway is used in England to fast-track patients with suspected colorectal cancer (CRC). This pathway aims to improve early detection of CRC and increase survival, with lower gastrointestinal (LGI) endoscopy considered the gold standard diagnostic test. The COVID-19 pandemic significantly impacted the 2ww referral

pathway. At the start of the pandemic, national guidance advised pausing all but emergency endoscopic procedures.¹²

Several predictors for CRC are recognised, including clinical symptoms, iron deficiency anaemia (IDA) and faecal immunochemical test (FIT) results.^{3–5} Studies report a higher risk of CRC when some symptoms present in combination rather than in isolation, in particular, rectal bleeding or IDA with other symptoms.^{6,7} These predictors of CRC were used in a two-stage triage pathway to expedite investigations in those at greatest CRC risk. The first stage used FIT results and symptoms to identify those at a higher risk of CRC, who were then considered for a CT scan. The second stage used these results to prioritise endoscopy urgency when services resumed.

METHODS

Patient cohort

The Sheffield Teaching Hospital's (STH) two-stage pathway was prospectively applied to patients who were awaiting a 2ww LGI endoscopy at the time endoscopy services were paused in March 2020 and those referred until July 2020 when delays in endoscopy were reduced. Investigations performed up until November 2020 were included in the analysis.

The first stage of the pathway involved a case notes and laboratory data review by consultant gastroenterologists. Patients were categorised as having either a high, standard or low risk of CRC based on their FIT result and clinical symptoms. FIT results $>60 \mu\text{gHb/g}$ were considered to indicate a high risk, $10\text{--}60 \mu\text{gHb/g}$ a standard risk and $<10 \mu\text{gHb/g}$ a low risk of CRC. These thresholds were chosen based on FIT data describing the risk of CRC in patients with high-risk symptoms; these indicated that an FIT $<10 \mu\text{gHb/g}$ had a $<1\%$ risk of CRC, an FIT $10\text{--}59 \mu\text{gHb/g}$ had a 2.6% risk of CRC, whereas a FIT $60\text{--}100 \mu\text{gHb/g}$ was associated with a 7.3% risk of CRC and patients with a FIT $>100 \mu\text{gHb/g}$ had a 20.7% risk of CRC.⁸ Referrers were asked to provide an FIT result for 2ww referrals, apart from those with rectal bleeding or a palpable mass, although it was not mandated. In patients without an FIT result, clinical symptoms were reviewed and categorised as high, standard or low risk for CRC (table 1). Patients with symptoms that did not fulfil National Institute for Health and Clinical Excellence (NICE) Guideline NG12 criteria and those who had undergone a colonoscopy in the last 3 years, were categorised as low risk of CRC.

Case notes were also reviewed to identify risk factors for COVID-19 complications, including comorbidities and age, with a threshold of >70 years. Patients judged to be at high risk of CRC, without risk factors for COVID-19 complications, were offered a CT scan while awaiting resumption of endoscopy services. Patients were informed that CT was a more accessible

Table 1 Risk of CRC based on FIT, Hb and symptoms

Risk of CRC	Symptoms
High risk	FIT $\geq 60 \mu\text{gHb/g}$ Where FIT not available IDA with Hb $<10 \text{g/L}$ Rectal bleeding with; Change in bowel habit, IDA, weight loss or abdominal pain IDA with; Weight loss, abdominal pain or a change in bowel habit
Standard risk	FIT $10\text{--}59.9 \mu\text{gHb/g}$ unless palpable mass Isolated IDA with Hb $\geq 10 \text{g/L}$ Isolated symptoms
Low risk	FIT $<10 \mu\text{gHb/g}$ unless palpable mass Colonoscopy in last 3 years Symptoms not fulfilling NICE guideline NG12 criteria

CRC, colorectal cancer; FIT, faecal immunochemical test; Hb, haemoglobin; IDA, iron deficiency anaemia.

intervention during the pandemic, but was not as accurate at diagnosing CRC as LGI endoscopy.^{9–11}

CT examination

Oral contrast was used to prepare patients for CT imaging.¹² Five mL omnipaque 350 was dissolved in 100 mL of water and consumed three times a day for 3 days, with a further dose in the morning of the scan. This preparation technique was previously offered to frail patients at this trust as a less invasive and time-consuming alternative to CT (virtual) colonoscopy, which was not available during the early phases of the pandemic over concerns regarding COVID-19 transmission. The CT findings were categorised as high risk where there were features highly suggestive of a cancer, medium risk when non-specific findings such as bowel wall thickening were found and low risk when the scan was reported as normal. Colonic mass lesions on CT were considered highly predictive of CRC and beneficial in endoscopy prioritisation, allowing earlier diagnosis and treatment.

Prioritisation of patients

The second stage of the triage pathway prioritised the urgency of LGI endoscopy based on the FIT test result, CT findings, clinical symptoms and whether they had undergone a colonoscopy in the last 3 years. A higher priority was also applied to those who had a prolonged delay in investigation, as delays in CRC diagnosis are associated with worse outcomes.¹³ This composite score was used to assign a level of endoscopy prioritisation (EP) as either EP1, EP2, EP3 or EP4 with EP1 having the greatest priority and EP4 having the lowest priority (table 2). The composition of groups was chosen based on the perceived cancer risk in each group and the endoscopy capacity.

Statistical analysis

The primary outcome measure was the detection of CRC in the four prioritisation groups. Statistical analysis was carried out using GraphPad software V.9 (USA),

Table 2 Prioritisation of colonoscopy when endoscopy services had resumed

Prioritisation of endoscopy	Criteria
EP1	Abnormal imaging/rectal mass suspicious of cancer* FIT >60 µgHb/g Patients >10 week on pathway (excluding polyps and FIT <10 µgHb/g)
EP2	Any risk and >8 weeks on pathway with no imaging High-risk symptoms with no imaging High-risk polyps Non-specific imaging abnormalities
EP3	High-risk symptoms and normal imaging Standard risk symptoms FIT 11–59 µgHb/g Standard risk polyp
EP4	FIT <10 µgHb/g Low risk polyps Symptoms not fulfilling NICE guideline NG12 criteria

*Patients found to have changes consistent with CRC on CT had an expedited LGI endoscopy performed by exception.
CRC, colorectal cancer; EP, endoscopy prioritisation; LGI, lower gastrointestinal; NICE, National Institute for Health and Clinical Excellence.

with significance set at a p value of <0.05. Categorical variables were summarised by descriptive statistics, including total numbers, percentages and relative risk with comparisons between groups performed using the χ^2 test or Fisher's exact test. Continuous variables were summarised by mean and SD.

Secondary outcome measures include alternative diagnoses such as inflammatory bowel disease, a non-colonic cancer and advanced polyps (defined as a polyp >1 cm, with high-grade dysplasia or villous histology). Univariate and multivariate binomial regressions using backward elimination were used to demonstrate factors associated with a CRC.

RESULTS

There were 514 patients referred for an LGI endoscopy during the study period (figure 1). There was an equal gender representation with 257 (50%) males and a mean (SD) age of 64.5 years (12.7 years). An FIT test was available in 194 patients (37.7%) with 40/194 (20.6%) having a result >100 µgHb/g, 7/194 (3.6%) had an FIT 60–99 µgHb/g, 79/194 (40.7%) had an FIT 10–59 µgHb/g and 68/194 (35.1%) had an FIT <10 µgHb/g.

The most common reason for referral was a change in bowel habit (47%) with a smaller proportion of patients having abdominal pain (27%), rectal bleeding (25%), IDA (23%) and weight loss (15%), with 43% having a combination of symptoms.

The first stage of the triage pathway judged the risk of CRC to be high in 190/514 patients (37.0%),

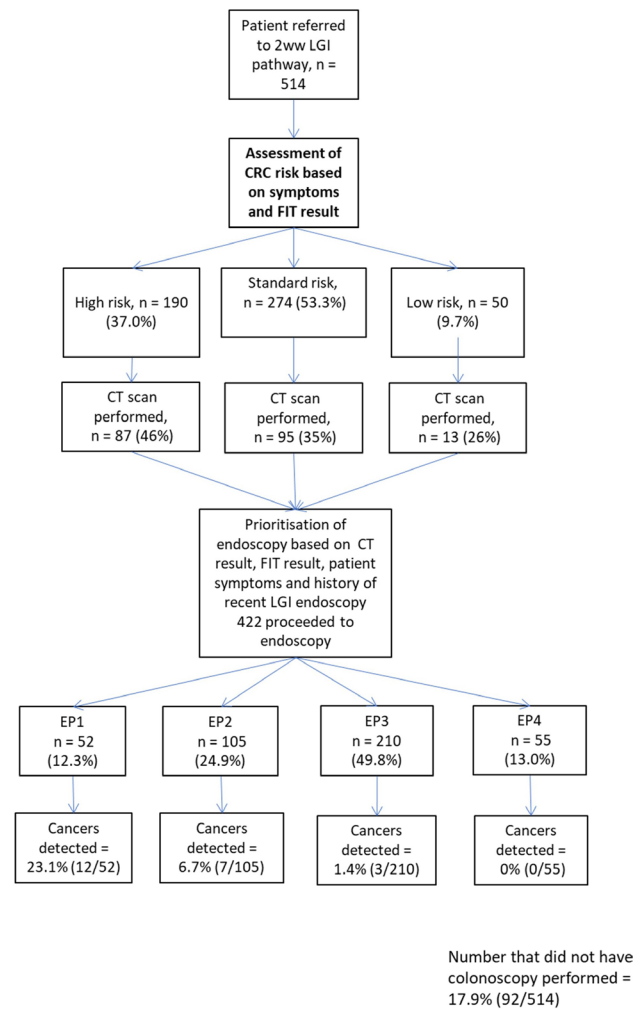


Figure 1 Study flow chart demonstrating proportion of patients deemed to be at high risk of CRC, CT scan provision and subsequent prioritisation of endoscopy. 2ww, 2-week wait; CRC, colorectal cancer; EP, endoscopy prioritisation; FIT, faecal immunochemical test; LGI, lower gastrointestinal.

standard in 274/514 patients (53.3%) and low in 50/514 patients (9.7%).

CT findings

Radiological imaging with a CT was performed in 195/514 patients (37.9%), of whom 158 subsequently had an LGI endoscopy. CT findings highly suspicious of cancer were reported in 15/195 patients (7.7%). Non-specific findings such as bowel wall thickening were reported in 18/195 patients (9.2%). Polyps were reported in two patients.

Prioritisation of colonoscopy

Following initial referral, 422/514 patients (82%) underwent a LGI endoscopy (see online supplemental information 1 for reasons patients did not proceed to endoscopy). The second stage of the triage pathway allocated 52/422 patients (12.3%) to the EP1 group with 105/422 (24.9%), 210/422 (49.8%) and 55/422

(13.0%) allocated to the EP2, EP3 and EP4 groups, respectively.

CRCs detected

CRC was detected in 22/422 patients (5.2%) who underwent endoscopy, with one further CRC detected at CT and operated on without undergoing LGI endoscopy. The mean (SD) age of patients with CRC was 70 years and 18/23 patients (78.3%) were male. Cancers were found in all parts of the colon with nine patients (39.1%) had rectal cancer, six patients (26.1%) had right-sided cancer, six patients (26.1%) had left-sided cancer, one patient had synchronous left-side and right-side cancers and one patient had anal cancer. When CT findings highly suggestive of CRC were reported, 13/15 patients (86.7%) were subsequently found to have cancer. A cancer was also found in a patient in whom a polyp was reported after CT imaging. No CRC was found in any of the patients with a normal CT report or with non-specific thickening. In the nine patients whose CRC were initially detected during endoscopy without a prior CT, six were seen on the subsequent staging CT and the other three had polyp cancers, which had all been removed prior to CT.

Patients categorised as having a high risk of CRC, based on FIT and clinical symptoms, had an increased prevalence of CRC 18/190 (9.5%) compared with those triaged as standard risk 5/274 (1.8%) (relative risk (RR)=5.2, 95% CI=2.0–13.7, $p<0.001$). There were no cancers in the low-risk group.

The second stage of the triage pathway, endoscopy prioritisation, performed well with a significantly higher prevalence of cancer in the EP1 group (12/52 patients (23.1%), RR=16.2, 95% CI 5.1 to 51.7, $p<0.001$) and EP2 group (7/105 patients (6.7%), RR=4.7, 95% CI 1.34 to 16.3, $p=0.018$) compared with the EP3 priority group (3/210 patients (1.4%)) (table 3).

Prior to recommencement of endoscopic services, 39 LGI endoscopies were performed by exception. Of these, CRC was diagnosed in eight patients (20.5%), of which seven had a prior CT suggestive of cancer.

Non-CRC findings

Advanced polyps were found in 47/400 patients (11.8%) who did not have CRC. Inflammatory bowel disease was diagnosed in 12/422 patients (2.8%). Relevant extra colonic disease was found in 9/514 patients

(1.8%), including 7 cancers (1 pleural, 2 renal cell, 1 cholangiocarcinoma, 1 hepatocellular, 1 pancreatic and 1 small intestinal neuroendocrine tumour) as well as 1 case of peritoneal tuberculosis and 1 of sarcoidosis.

Symptoms and FIT results

Most patients with CRC presented with a combination of symptoms (15/23 (65.2%)) rather than isolated symptoms (8/23 (34.8%)). The relationship between clinical symptoms and CRC is summarised in online supplemental information 2. FIT testing had been performed in 11/23 patients (47.8%) diagnosed with CRC. The FIT result was $\geq 10 \mu\text{gHb/g}$ in 10/11 of these patients and was $>60 \mu\text{gHb/g}$ in 6/11 patients. The single patient with an FIT $<10 \mu\text{gHb/g}$ had a palpable rectal cancer. The positive predictive value for an FIT $>60 \mu\text{gHb/g}$ was 13% with a negative predictive value of 98.1% for an FIT $<10 \mu\text{gHb/g}$.

Regression analysis

Factors associated with CRC diagnosis on univariate analysis were male sex, increasing age, an FIT $>60 \mu\text{gHb/g}$ and $>100 \mu\text{gHb/g}$, increasing number of symptoms, IDA with abdominal pain, rectal bleeding with abdominal pain and rectal bleeding with weight loss. Multivariate logistic regression analysis found that an FIT $>100 \mu\text{gHb/g}$ and rectal bleeding with weight loss remained independently associated with the presence of CRC (online supplemental file 3).

Patients not undergoing LGI endoscopy

LGI endoscopy was not performed in 92/514 patients (17.9%). Of these, CT imaging had been performed in 37/92 patients (40.2%) and 28/92 patients (30.4%) had undergone FIT analysis. This was $<10 \mu\text{gHb/g}$ in 15/28 patients (53.6%), $10\text{--}60 \mu\text{gHb/g}$ in 11/28 patients (44%) and $>60 \mu\text{gHb/g}$ in 2/28 patients (7.1%). The most common reason why endoscopy was not performed was patient choice to defer due to concerns regarding transmission of COVID-19 (see online supplemental file 1).

DISCUSSION

The COVID-19 pandemic dramatically limited the provision of endoscopy services.¹⁴ Therefore, a prioritisation system was required to minimise delays in cancer diagnosis. We used the availability of CT imaging to assess for evidence of CRC in those at

Table 3 Number of cancers per prioritisation group

Prioritisation group	Number LGI endoscopy performed	Number diagnosed with CRC	Percentage diagnosed with CRC	Relative risk (95% CI)
EP1	52	12	23.1	16.2 (5.1 to 51.7)
EP2	105	7	6.7	4.7 (1.3 to 16.3)
EP3	210	3	1.4	1
EP4	55	0	0	0 (0 to 4.7)

CRC, colorectal cancer; EP, endoscopy prioritisation; LGI, lower gastrointestinal.

highest risk and minimise diagnostic delays. This pragmatic approach prioritised more than half of all CRC cases to the most urgent group, which comprised of only a tenth of the patients. Most of the remaining cancers were in the next highest priority group leaving only 13% of CRC patients in the EP3 group.

This is the first study to describe the outcomes of an endoscopy prioritisation system that considered the results of CT imaging alongside clinical symptoms and FIT results. There were no CRCs detected in patients whose CT scans were reported as normal; however, 37 of these patients did not undergo endoscopy. Although this strategy may have missed patients with early or small cancers, it suggests that in the setting of reduced endoscopy capacity a CT examination in those at high risk of CRC based on FIT and clinical symptoms is a reasonable strategy to reduce time to diagnosis. This provides reassurances to both patients and relevant stakeholders regarding investigating safely and in a timely manner. The downside of this strategy is the additional burden on radiology departments and increased exposure to ionising radiation, as just over a third of patients had high-risk features based on symptoms and FIT results. There are also additional resources associated with the risk prioritisation process, although this would be minimised by a greater use of FIT testing.

Based on FIT alone, 10 of the 11 patients with CRC would have been detected at a level $\geq 10 \mu\text{gHb/g}$ and the single patient with an FIT $< 10 \mu\text{gHb/g}$ had a palpable rectal cancer. The limitation of FIT in patients with rectal lesions is well recognised and the findings at rectal examination should be considered alongside the FIT result.¹⁵ Our data is consistent with the findings of previous studies which have reported a sensitivity of 90.9%–97% and a negative predictive value (NPV) of 99.8%–98.9%, with an FIT of 10–150 $\mu\text{gHb/g}$.⁵ This supports the use of a FIT level $< 10 \mu\text{gHb/g}$ in combination with a normal rectal examination as a safe method to exclude patients from a cancer pathway.

Despite communications to primary care clinicians and subsequent patient letters, disappointingly, an FIT result was available in only 38% of patients. Maclean *et al* demonstrated FIT results could be obtained in over 94% of referrals by sending the kit directly to patients and, using a 10 $\mu\text{gHb/g}$ cut-off, a half of the patients were excluded from further investigations.¹⁶ If this were applied in our cohort, 35.7% of the patients with an FIT result would have been excluded. We believe FIT testing should be considered imperative for all 2ww referrals without a mass or rectal bleeding, and we recognise this was recommended by a recent independent review of diagnostic services for NHS England.¹⁷

Almost a fifth of patients did not proceed to endoscopy following referral. Patient choice was the reason in over half of cases with 20.6% deferring due to

the pandemic. Anxiety to undergo endoscopy during the pandemic has been described.¹⁸ This high rate of incomplete investigations is a further indication of this. However, this concern does not appear to be justified, with a UK multicentre study of 6208 patients, undertaken after the first lockdown, reporting no cases of COVID-19 transmission.¹⁹ The long-term outcomes associated with decisions to decline investigation were uncertain and worthy of further research.

Abnormalities were seen on the CT of all 13 patients who underwent CT before endoscopic confirmation of CRC.¹² However, 37 patients did not go on to have LGI endoscopy after their CT. Studies of CT examinations have reported a CRC miss rate between 0% and 30%, and this predominantly relates to the early CRC associated with the best prognosis.^{9–11} Therefore, if there were significant endoscopy restrictions again, we would advocate CT with oral contrast as an endoscopy prioritisation tool but not a definitive method of CRC exclusion.

This study was limited to a single centre and 23 patients with CRC. Planning a coordinated response with little notice during the height of a pandemic is challenging. Regardless, FIT and CT imaging are widely available and, therefore, the study outcome is applicable to many centres.

A major strength of this study is that it is a ‘real-world’ prospective study with incomplete endoscopy investigations highlighting patient concern related to COVID-19 during hospital attendance. Accepting these limitations, this prioritisation strategy effectively allocated most patients with CRC to the highest endoscopy priority groups.

CONCLUSION

The COVID-19 pandemic has, and continues, to affect the delivery of endoscopy services. Utilisation of CT imaging in those at highest risk of CRC is an effective strategy to prioritise endoscopy during a period of limited endoscopy capacity.

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