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An assessment of Colorectal two week wait referrals, the impact of COVID-19 and the use of FIT to rationalise appointments, a single centre audit

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Abstract

Aim

This single-center audit aimed to assess the impact of COVID-19 on the 2WW Colorectal cancer (CRC) service and analyze the impact of types of the initial assessment. We ask what impacts compliance with 2WW standards, and can we find ways to improve this?

Methods

Data were collected from January, April, May, and November. These were considered as pre-COVID, 1st lockdown (April/May), and 2nd lockdown. Analysis was performed on compliance with national 2WW standards, initial assessments, investigations, pre-op staging, fitness for surgery, and the impact of FIT testing.

Results

Of 1060 referrals, 58 had CRC. The number of referrals dropped in April (158) from January (204), then increased to 438 in Nov. The proportion of CRC varied across the year, from 3.7 to 8.1 %. Standards were poorly met and worsened through the lockdowns. The average time to colonoscopy increased from Jan to Nov (21 to 54 days). There was a significantly increased risk of CRC with an abnormal FIT test (p=0.04). The percentage of patients unfit for surgery increased from January to November (12.5 to 34 %). Pre-operative T staging was significantly worse in November compared to January (p=0.05).

Conclusion

Compliance with national standards declined over the lockdowns. We have demonstrated delays in the gold-standard investigation. The pandemic has potentially led to more unfit patients and higher T staging. This study demonstrates areas within the 2WW cancer pathway affected by COVID-19 and calls for more rationalization of resources and the potential use of compulsory FIT testing to triage the 2WW referrals.

Keywords: Colorectal cancer, 2 week-wait, COVID, coronavirus

Introduction

Early detection and initiation of treatment are well known to lead to better outcomes for colorectal cancer (CRC), with improved morbidity and mortality **[1]**. Two week-wait (2WW) cancer pathways have been run throughout the NHS since 2000 **[2]** but still, national standards are not met, therefore we must continue to find ways to optimize pathways.

Coronavirus has put strains on the NHS, with cancer services being no exception. There have been reduced theatre lists, face-to-face clinics, altered staffing, and restrictions on invasive investigations and screening **[3]**. It is clear the pandemic has caused delays in cancer diagnosis and treatment **[4,5]**. Amongst these pressures the standards for 2WW referrals have not changed, meaning departments have been under pressure to adapt their services to maintain standards, providing opportunities to analyse the impact of changes to the pathway.

National standards intervals are as follows; standard 1 receipt of referral to the first appointment within 14 days (standard 93 %); standard 2 receipts of referral to date patient is informed of diagnosis or ruling out of cancer within 28 days (standard 75 %); standard 3 decision to treat to first definitive treatment within 31 days (standard 96 %); standard 4 receipts of referral to first treatment within 62 days (standard 85 %) **[6]**.

Our primary aim was to audit the 2WW referral pathway and to ask if national standards were being met, whilst assessing the impact of different methods of triage and initial assessment that affected these targets. The secondary analysis looked at the pre and post-operative staging, patient's fitness for surgery, and the use of fecal immunochemical testing (FIT) test as part of the referral process.

Methods

In this single-trust audit, we collected data across 4 cycles over 11 months. The local cancer services department supplied 2WW CRC referrals and clinical notes were reviewed on the electronic paper record. All referrals from January, April, May, and November 2020 were included. These were considered as pre-COVID, first lockdown (April and May), and second lockdown respectively.

Data collected included demographics (age, gender), the relevant dates (referral, first clinic appointment, investigation, treatment), first appointment type, FIT test result, information about diagnosis (pre-op and post-op staging), and if the patient was treated or not fit for surgery.

Data were analysed in Excel. The percentage of patients meeting each standard was calculated for each month. For each cycle, analysis was done on the proportion of each type of initial assessment (virtual/face-to-face OP/telephone OP) and the chosen test. A comparison was then made across the cycles. The number of patients presenting at each cancer stage was calculated and again this was compared. FIT testing was introduced to the referral criteria in November. This data was analysed to look at whether referrals included a result and whether negative or positive patients ended up having cancer. Finally, we compared the level of fitness of the patients with CRC. Where differences in proportion are estimated, fixed binomial distributions are assumed, and where the probability of the outcome is less than 5% their difference is deemed significant. Where differences in time are estimated, the probability of outcome means have been bootstrapped from the measured distribution of time intervals, and the probability of similar means is then estimated by sampling.

Results

The total number of referrals was 1060. Of these 58 had CRC. The volume of referrals increased across the year from 212 in January to 438 in November, with an initial drop in the first lockdown. The percentage of CRC diagnosis increased from 3.7 % pre-covid to 8.1 % at the end of the first lockdown, then dropped again in the second lockdown **(Table 1).**

There was poor compliance with the standards throughout the study, with the exception of standard 1. Standard 1 was met for each cycle of data collected, with compliance of 100 % in May. Standard 2, was only met in January then declined to 61, 51, and 41 % of referrals, from April to Nov respectively, not meeting the target. Standard 3 was met with 100 % in January but significantly declined through the year to 50, 33, and 66 % of referrals not meeting the target. Standard 4 was not met from January to November with 50, 80, 55, and 68 % respectively, not meeting the target.

Table 1: Key results

Month	January	April	May	November
Number of referrals	214	163	247	438
Number of CRC diagnoses (%)	8 (3.7)	5 (3.1)	20 (8.1)	25 (5.7)
Pre-op T staging (% T3/4)	3 (1.4)	3 (1.8)	13 (5.3)	14 (3.2)
Post-op T staging (% T3/4)	3 (1.4)	1 (0.6)	9 (3.6)	5 (1.1)
Not Fit for surgery (%)	12.5	25	25	34

In April and May, the majority of initial assessments were telephone appointments. In January and November, they were virtual (straight to test from triage). There was no significant difference in the time to test for different types of assessments.

The percentage of each type of investigation varied across the year. The volume of colonoscopies decreased in the first lockdown from 70 % to 49 %, then gradually increased to 52 % in November. There was an increase in the percentage of CT scans (3, 13, 13, 7 %) and CT colonoscopies (19, 35, 29, 29 %) from January to November. The mean time for colonoscopy increased from 21 days in January to 54 days in November ($p < 0.0001$). There was no delay in time to CT scan or CT colonoscopy.

Across the year the percentage of patients diagnosed with CRC who were deemed unfit for surgery increased from 12.5 % in January to 34 % in November.

In November the trust introduced FIT stool analysis to the referral process. Of the 438 referrals, 55 % did not include a FIT test. A possible 8 % did not require one (either PR bleeding or Iron deficiency anaemia (IDA). Patients diagnosed with cancer were 4 times more likely to have an abnormal (> 10mg Hb/g) result than a normal one (< 10mg Hb/g) ($p\sim0.04$).

The pre-operative T staging of patients across the year significantly worsened ($p\sim0.05$). Postoperative T staging shows no significant trend. There was no significant difference in nodal or metastatic staging.

Discussion

All secondary care departments struggle with large volumes of 2WW cancer referrals, of which the majority will not end up with a cancer diagnosis. However, it is vital that these referrals are handled in timely and efficient ways in order to quickly diagnose those with malignancy. Therefore, safe methods of triaging and rationalizing referrals are needed to prevent delays in treatment. The Coronavirus has clearly only increased these pressures. This study demonstrates this negative impact but adds to the evidence for a potential solution with the FIT.

The number of referrals increased across the year; therefore, it is even more important that departments improve referral pathways to effectively use resources. Triaging should rationalize resources such as colonoscopies and clinic appointments but contrary to expectations and previous studies **[7,8]** during the pandemic we have not demonstrated that the mode of initial assessment impacts the time to diagnosis. However, there is evidence that compulsory FIT testing for CRC referrals could be a safe way to triage patients and rationalize urgent 2WW appointments for those with a positive test. Previous studies have demonstrated that FIT safety highlights patients with high-risk or low-risk diseases and would therefore help to prioritize patients **[9,10]**. Here three patients with a normal FIT test did have a positive diagnosis however, of these 2 had IDA and were exempt from the test and one was diagnosed with a benign polyp.

We propose that FIT testing becomes a compulsory element of a CRC 2WW referral. If a test has not been performed it should be rejected or 'placed on hold' and the GP contacted urgently to arrange the investigation. If the result is normal (< 10mg Hb/g) then a referral can be downgraded to urgent or routine. Then finally those with a positive FIT can be prioritized as we have demonstrated they are 4 times more likely to have a positive finding.

Patients in this study were failing to receive the gold standard diagnostic investigation **[11]** within the proposed time period. This delay remained even when colonoscopy lists had returned to normal, demonstrating that the delay seen was likely secondary to a backlog of patients. These drawn-out processes have negative impacts on those diagnosed with cancer and those not. You cannot deny the anxiety and stress associated with awaiting a potential diagnosis of cancer. This highlights the need for intervention prior to the initial investigation, strengthening the argument for compulsory FIT testing. Furthermore, only 45 % of referrals included a FIT, therefore, the number of patients who could be safely downgraded has the potential to be much higher.

One significant finding of note in this study was the increase in the number of patients deemed unfit for surgery. It is difficult to ascertain exactly why this was seen given there wasn't an increase in metastatic disease. Could it be a result of the lockdowns themselves having a broader impact on patients' health?

Finally, it is important to consider the possible consequences of higher average T staging in the second lockdown. Although beyond the scope of this study, interesting questions include did patients have more positive margins, more difficult surgeries, or perioperative complications? Will there be an impact on recurrence rates and prognosis?

This study has some limitations. Firstly, the sample size. With only 58 cancer diagnoses, there was a low chance of identifying significance for secondary outcomes. The study was initially designed to assess pre, during, and post COVID. With the unpredicted length of the pandemic, we have not been able to analyze the complete cycle and assess whether the system has now returned to a normal state. It is unclear how long these negative impacts will persist.

There are huge pressures on all areas of the healthcare system, worsened by the pandemic, and we need to find ways to rationalise and improve the efficiency of our practice in order to meet national standards and improve patient outcomes. We propose that we need to be stricter with 2WW referrals by including compulsory FIT tests and use these results to prioritise positive patients and downgrade negative tests. Discussions with local cancer services are in progress but changes to the system must be made urgently to deal with the increasing backlog and the unknown pressures in the future.

Declarations: None

Conflict of interests: There are no conflicts of interest to be declared.

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