Associations between patient factors and successful colon capsule endoscopy – a prospective cohort study

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Conflict of interest disclosure

We declare no conflicts of interest related to this article.

Ethical approval

Research ethics approval for this study was obtained from the South Central – Hampshire B Research Ethics Committee (20/SC/0378).

Patient consent statement

Caldicott guardian approval was obtained for the use of the patient data from the ScotCap evaluation and collection of additional data.

Funding statement

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Author Contributions

Data collection: C MacLeod. *Study statistician:* A Foxton. *Data analysis:* C Macleod, A Foxton, P Wilson, S Treweek, AJM Watson. *Manuscript writing and drafting:* C Macleod. *Conceptualisation:* C MacLeod, AJM Watson. *Manuscript editing:* C Macleod, P Wilson, S Treweek, AJM Watson.

Abstract

Aim

To establish patient factors associated with a successful colon capsule endoscopy (CCE) test.

Methods

This prospective cohort study used data collected from patients who underwent CCE as part of the ScotCap evaluation prior to April 2020. A CCE was defined as successful if the capsule visualised the whole colon and rectum (complete test) with sufficient bowel cleansing to assess the colonic mucosa (adequate bowel preparation). Symptomatic and surveillance patient factors were analysed for associations with a successful test, complete test, adequate bowel preparation and requirement for further procedure using univariate, multivariate logistic, and least absolute shrinkage and selection operator regression.

Results

Data from 263 symptomatic and 137 surveillance patients were analysed. There was an association between symptomatic patient's age and successful test (Odds ratio [OR] 0.97, 95% confidence interval [CI] 0.95-0.99), adequate bowel preparation (OR 0.97, 95% CI 0.94 – 1.00) and further procedure requirement (OR 1.04, 95% CI 1.02-1.06). Symptomatic patients with a faecal immunochemical test result between 10-399 µg/g were associated with a further procedure (OR 2.32, 95% CI 1.23 to 4.48). Patients undergoing surveillance for previous colorectal cancer (OR 0.42, 95% CI 0.18-0.97), who had previous bowel resection surgery (OR 0.43, 95% CI 0.19-0.98) or were on beta blocker medication (OR 0.32, 95% CI 0.11-0.88) were associated with further procedure requirement.

Conclusions

Younger age was associated among symptomatic patients with obtaining a successful test. Clinicians could consider patient selection based on these results to improve the rate of successful testing in clinical practice.

What does this paper add to the literature?

Optimising patient selection may improve the outcomes for CCE. We have identified patient factors associated with a successful test, adequate bowel preparation and the need for further procedure following CCE. These factors may help guide clinicians when choosing patients for CCE.

Introduction

Colon capsule endoscopy (CCE) is an alternative to colonoscopy and CT colonography (CTC) for investigating lower gastrointestinal (GI) disease. CCE involves a patient swallowing a capsule containing a camera at each end to capture 50,000 images of the GI tract and transmit them to a wireless receiver. As with colonoscopy, patients need standard bowel preparation to cleanse the colon prior to the procedure. However, more laxatives (boosters) are required after capsule ingestion to help propel the capsule through the GI tract [1]. Published research has shown CCE to have diagnostic accuracy comparable to CTC[2,3].

A CCE test can be defined as "successful" if it is complete, and the overall bowel preparation is adequate. A CCE can be considered complete if the whole colon and rectum is visualised within the battery life of the capsule. Published completion rates (55-100%) and rates of adequate bowel preparation (40-100%) for CCE vary substantially [3,4]. Despite the use of different bowel preparation and booster regimens, the rates of successful tests for CCE do not match those for colonoscopy or CTC [5]. The benefits of the less invasive CCE are lost if patients who do not obtain a successful test require further assessment by colonoscopy, CTC, or flexible sigmoidoscopy rather than proceeding to a targeted therapeutic procedure for the pathology identified by CCE.

Multiple patient factors influence gut motility and these will affect the successful test rates of patients undergoing CCE [6]. Furthermore, a patient's compliance with the bowel preparation and booster regimen will also influence the chances of obtaining a successful test. Advanced diverticular disease, colonic elongation or tortuosity, and older age are known predictors of incomplete colonoscopy [7,8]. The patient factors influencing the rate of successful CCE tests are, to date, unknown. In this study we aimed to establish the factors associated with a successful CCE test.

Methods

Data sources and ethics

Patient data collected in the ScotCap evaluation were used in this prospective cohort study [9]. Two groups of patients were recruited to the ScotCap evaluation: symptomatic and surveillance. Symptomatic patients were referred by their general practitioner with new gastrointestinal symptoms for investigation and had been assessed as requiring a colonoscopy by a secondary care consultant. Surveillance patients were those on the waiting list for surveillance colonoscopy due to increased risk of developing colorectal cancer (CRC). The inclusion and exclusion criteria for the ScotCap evaluation is detailed in Table 1. In the current study we included patients from a single geographical health board (NHS Highland), the largest subset of those in the ScotCap cohort, who underwent CCE during the ScotCap evaluation up to April 1st, 2020. Ethical approval was not obtained for the use of patients data from NHS Grampian and Western Isles, and those who underwent CCE after April 1st, 2020 hence their exclusion from the study. Further details of patient recruitment, and data collection in the ScotCap evaluation are described elsewhere [9].

Patients underwent CCE procedures using the PillCam™ COLON 2 (Medtronic, UK). The bowel preparation and booster regimen, and dietary restrictions used for the ScotCap evaluation are detailed in Appendix 1 Table 1. A specialist nurse carried out CCE procedures following a protocol (Appendix 2). CCE procedure images were reviewed by 2 NHS Scotland consultant gastroenterologists trained in CCE reading, who produced a report detailing if the CCE procedure was complete, if the bowel preparation was adequate and details of any pathology detected by the

capsule anywhere in the visualised GI tract. CCE reports were returned to the referring secondary care clinician who decided on further patient management.

We defined a "successful test" as a CCE procedure which was complete and the bowel preparation was adequate. A "complete test" was defined as a CCE procedure which visualised the whole colon and rectum within the battery life of the capsule. The bowel preparation was determined to be "adequate" if the if rated as at least 'fair' in all colonic segments and the overall quality was deemed to be adequate by the CCE reader. The bowel preparation was assessed and rated according to the Boston bowel preparation scale [10]. Significant pathology, identified by CCE, was defined as any finding requiring follow up according to European guidelines [11]. A patient was regarded as requiring a further procedure if they underwent or were scheduled to undergo a colonoscopy, flexible sigmoidoscopy, CTC, clinic review or laparotomy following CCE by the end of the evaluation, irrespective of whether the CCE procedure was successful or not.

Additional patient data were collected to supplement the ScotCap evaluation data. Patients' medical conditions, medication, previous bowel resection surgery and body mass index (BMI) data were collected by a clinical researcher (CM) from patients' secondary care electronic health records. Medical conditions and medications were categorised using ICD-11 and the British National Formulary, respectively [12,13]. Medical conditions, medications and their categories are listed in Appendix 3 Table 1.

Caldicott guardian approval was obtained for the use of the patient data from the ScotCap evaluation and collection of additional data. Research ethics approval for this study was obtained from the South Central – Hampshire B Research Ethics Committee (20/SC/0378). This study was funded by an NHS Highland Research Development and Innovation grant. The protocol for this study is available online (https://mfr.osf.io/render?url=https://osf.io/vypqk/?direct%26mode=render%26action=download%26mode=render).

Aims

The primary aim was to identify patient factors (Appendix 4 Table 1) associated with a successful CCE procedure (a complete test with adequate bowel preparation). A secondary aim was to determine any patient factors associated with further procedure requirement following CCE. We also analysed whether any patient factors were associated independently with a complete test (visualisation of the whole colon and rectum) or adequate bowel preparation (a bowel preparation rating of at least fair in all colonic segments and determined as adequate overall by the CCE reader).

Statistical analysis

Statistical analysis was conducted using R. Symptomatic and surveillance cohorts were analysed separately. Baseline characteristics were expressed as means with standard deviation for continuous variables and absolute numbers and percentages for categorical variables. Univariate and multivariate logistic regressions were performed, along with least absolute shrinkage and selection operator (LASSO) regression for variable selection. LASSO was used as it can effectively shrink the coefficients for nonessential variables to zero while retaining the most relevant ones for predicting desired clinical outcomes[14]. The model used for this data analysis was calibrated to manage the number of variables being examined. Cross-validation (10-fold) was used during LASSO regression to find the value of lambda, which was identified when the cross-validation error was at a minimum. The variables selected were considered in a multivariate logistic regression. The results from both the univariate and multivariate regression analysis were expressed as odds ratios (OR) and 95%

confidence intervals (CI). To minimise reduction in sample size, variables such as BMI, haemoglobin (Hb) count, estimated glomerular filtration rate (eGFR) and faecal immunochemical test (FIT) results were not included in the multivariate logistic regression due to the volume of missing values. Instead, univariate logistic regression was performed on these variables. For all these tests, a significance level of 0.05 was used.

Results

Of the 733 patients in the ScotCap evaluation, 401 NHS Highland patients were included in this study (Figure 1). Patient data for 263 symptomatic patients and 147 surveillance patients were analysed. The demographics and CCE outcomes for these patients are described in Tables 2 and 3. The mean age of patients was 60 and 62.7 years in the symptomatic and surveillance cohorts, respectively. The proportion of patients who were female was 44.5% and 42.3% in symptomatic and surveillance cohorts, respectively. In the symptomatic cohort the most common referral urgency rating was urgent suspected cancer (39.2%), and the most common referral symptom was change in bowel habit (68.1%). The proportion of patients in the symptomatic cohort with a FIT result <10µg/g, 10-399µg/g and >400µg/g was 35%, 30% and 1.5%, respectively. The remaining 33.5% of symptomatic patients did not have a FIT result available. The most common reason for patients undergoing colonic surveillance was previous polyps (53.6%). The proportion of patients obtaining a complete test, adequate bowel preparation, a successful test and requiring a further procedure in the symptomatic cohort was 72.6%, 80.2%, 66.2% and 62.4%, respectively. In the surveillance cohort, the proportion of patients obtaining a complete test, adequate bowel preparation, a successful test and requiring a further procedure was 71.5%, 65%, 55.5% and 67.9%, respectively.

Patient factors with a statistically significant association with a successful test, adequate bowel preparation and further procedure requirement are shown in Tables 4 and 5 for the symptomatic and surveillance cohort, respectively. On multivariate analysis with LASSO variable selection, the age of symptomatic patients was associated with the rate of successful test (p=0.02, OR 0.97, 95% CI 0.95-0.99) and further procedure requirement (p<0.001, OR 1.04, 95% CI 1.02-1.06). There was an association between patients in the surveillance cohort undergoing surveillance due to colorectal cancer surgery follow up and further procedure requirement (p=0.04, OR 0.42, 95% CI 0.18-0.97) on multivariate analysis with LASSO variable selection. On univariable analysis, symptomatic patients age was associated with adequate bowel preparation (p=0.04, OR 0.97, 95% CI 0.94-1.00) and symptomatic patients with a FIT result 10-399µg/g were associated with further procedure requirement (p=0.01, OR 2.32, 95% CI 1.23 to 4.48). In the surveillance cohort, patients who had undergone previous bowel resection surgery (p=0.04, OR 0.43, 95% CI 0.19-0.98) or were on beta blocker medication (p=0.03, OR 0.32, 95% CI 0.11-0.88) were associated with associated with further procedure requirement on univariable analysis. The results for the analysis of the remaining factors are shown in Appendix 3 Tables 1-10.

Discussion

In this prospective cohort study, we found that the age of symptomatic patients was associated with a successful test and adequate bowel preparation. Age appears to be a potential predictive factor for patients obtaining a successful test when undergoing CCE. The underlying mechanism for these results may be this group's ability to complete the bowel preparation regimen required for CCE. Although these results do not imply causality and the associations found for both patient groups were of low magnitude (OR 0.97 and 0.97), clinicians could consider patient selection based on these results to improve the rate of successful testing in clinical practice.

No patient factors examined were independently associated with an improved test completion rate. CCE test completion rates may be limited by current technology as battery life is a likely limiting factor. However, more promisingly, the introduction of prucalopride as a booster has recently been shown to increase the complete test rate [15]. The use of prucalopride should be explored in other patient populations as our findings suggest refining patient selection for CCE may not improve the complete test rate.

The successful test rate of CCE is an important measure of test performance which allows comparison with other colonic investigations. However, this rate does not take into account the presence of pathology and the effect this has on follow up procedure requirements. Future research may require a more pragmatic approach as the need for colonoscopy following CCE is primarily driven by pathology [9]. For example, in the ScotCap evaluation, 92% of colonoscopies required for patients following CCE were due to pathology identified by the capsule. Recent CCE publications have reported the rate of conclusive test (a successful test or a test with any findings requiring endoscopic follow up) to better describe the value of CCE and we suggest this rate is routinely reported in future clinical studies evaluating CCE [15].

Patient selection will be important to reduce the need for further procedures post CCE and to avoid associated costs for both patient and health service. Our results suggest that symptomatic patient age and FIT results between 10-399 µg/g were associated with a further procedure following CCE. It is well established that FIT is a valuable test for predicting the risk of underlying colorectal pathology in those with relevant symptoms, however the risk of harbouring colorectal cancer varies significantly in the 10-399 µg/g range from 1.9% to 22.4% [16–18]. Finding the optimum FIT range for CCE should be an aim of future research as the use of FIT prior to CCE will be important when determining which patients are best suited for the test.

Recruitment to the surveillance cohort during the ScotCap evaluation was halted due to a higher follow up procedure rate compared to the symptomatic group [9]. However, these results suggest that those undergoing surveillance colonoscopy due to previous colorectal cancer or having had a previous large bowel resection were associated with a lower rate of follow up procedure. The presence of colorectal pathology is comparatively low in patients who are undergoing surveillance colonoscopy following colorectal cancer surgery, and a shorter colon will reduce the amount of mucosa requiring visualisation by the capsule [19,20]. The use of beta-blocker medication was also found to be associated with a reduced rate of follow up procedure requirement in the surveillance cohort on univariable testing. It is unclear what the mechanism for this result is and should be further investigated in future work.

A comparable study to ours conducted by Moen et al has recently been published [21]. In their similarly sized study (n=451), they found a range of predictors associated with a complete test, including increased patient age, which contradicts our results. Patient data used in Moen et al.'s study were from an epidemiological study and the booster regimen used was also different compared to that used in our study, which may explain the differences in results. In addition, the complete test rate was higher in our study (72.3% vs 51.9%) which may have provided greater power for statistical analysis. These differing results may also reflect the challenges of generalizing results to different populations and patient selection for CCE.

Our results should also be compared to those reported in a recently published observational cohort study by Gimeno-García et al [22]. Their results demonstrated that no variables were associated with CCE device excretion rate (complete test rate) further supporting our conclusions. Gimeno-García et al. similarly found that age was negatively associated with the rate of adequate bowel preparation

on univariate analysis, despite the use of different bowel preparation and booster regimens. In addition, Gimeno-García et al. identified constipation as a strong predictor of poor bowel cleansing. We did not identify constipation as a factor associated with inadequate bowel cleansing, however the prevalence of constipation in our study was low (8.7% of symptomatic patients) as slow transit constipation was an exclusion from recruitment to the ScotCap evaluation.

Strengths and limitations

One of the strengths of this study is the data source. The ScotCap evaluation is the largest evaluation of CCE use in a symptomatic patient population. In addition, CCE procedures in the ScotCap evaluation were carried out in line with a protocol using a consistent bowel preparation and booster regimen, and dietary instructions throughout to improve reproducibility of CCE outcomes. However, further research may be required to establish if these results are applicable to different bowel preparation regimens and newer CCE devices, if available.

There are some limitations to our study. Only data from one NHS Scotland health board was used in this study, potentially limiting generalisability. Some data were not available for all patients such as BMI, or FIT, limiting their inclusion in multivariate analysis. We also acknowledge additional data collection for this study was carried out retrospectively with a risk of reduced data quality and completeness. Finally, patients' medical conditions and medications were categorised into broad categories which may have reduced the specificity of the result analysis.

Conclusion

In this study, we found that younger age was associated with obtaining a successful test. Symptomatic patients with a lower FIT result or those undergoing surveillance due to previous colorectal cancer may also be more suitable for CCE if the need for further procedure is a concern. Findings are limited to the sample used in this study and therefore further research on different or larger dataset may be required to support these results given the novelty of this work. These results may be considered by clinicians when selecting patients to undergo CCE to achieve a better successful test rate and lower follow up procedure rate.

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Figure 1. Study profile flow diagram.

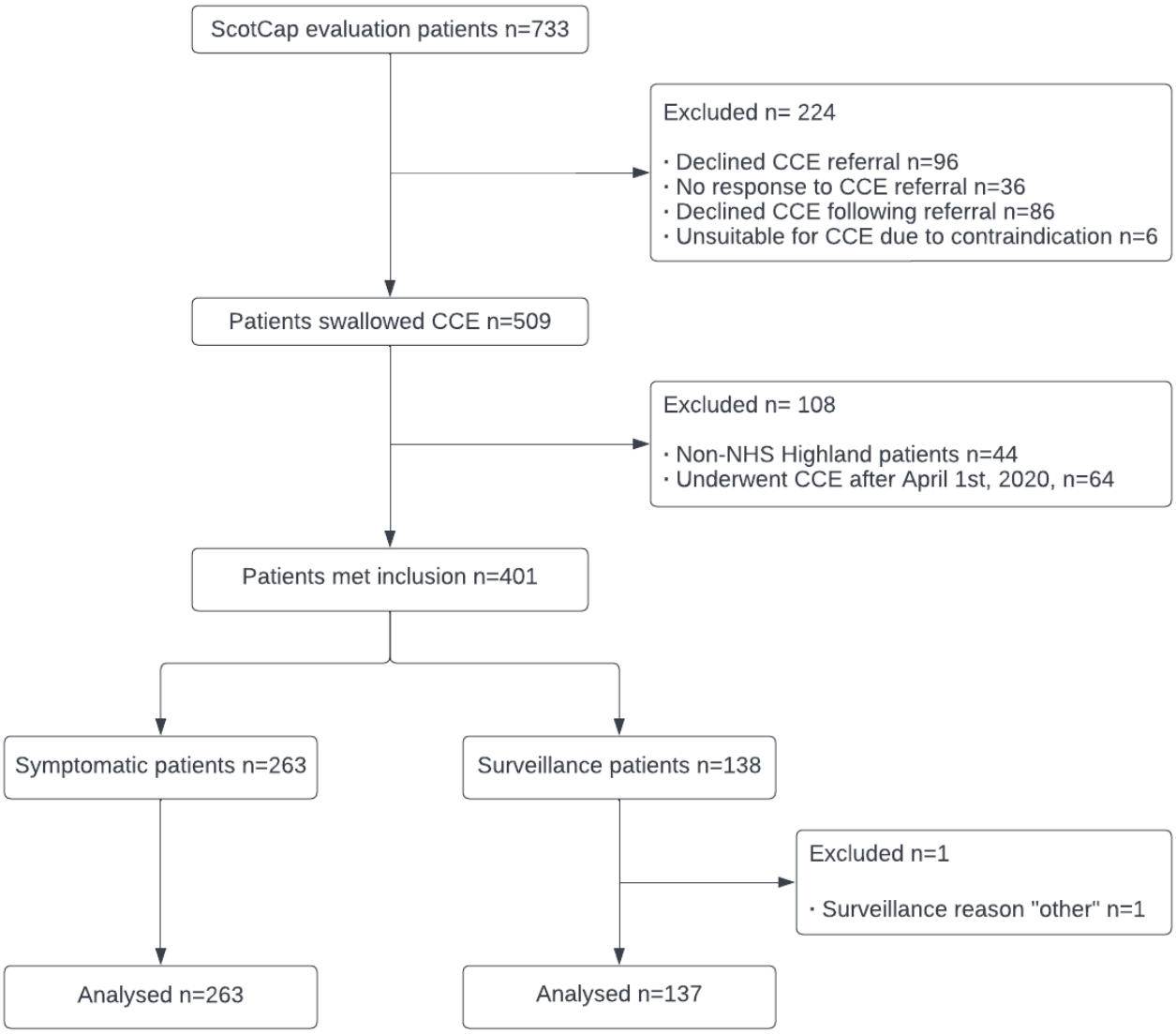

Table 1. Inclusion and exclusion criteria for the ScotCap evaluation

Patient type	Inclusion criteria	Exclusion criteria
All	• Over 18 years of age • Able to provide valid consent	• Difficulty swallowing • Indwelling electromedical device • Insulin dependent diabetes mellitus • History of small or large bowel strictures • Pregnant women • Medically unfit to take full bowel preparation
Symptomatic	• Referred from primary care with lower gastrointestinal symptoms and assessed as requiring a colonoscopy by a secondary care consultant	• Predominant referral symptom diarrhoea or slow transit constipation • FIT >400 • Microcytic anaemia sole investigation reason
Surveillance	• Due surveillance colonoscopy in the month before, during and month after recruitment period • Personal or family history of colorectal cancer • History of colonic polyposis • Hereditary non-polyposis colorectal cancer (HNPCC)	• Familial adenomatous polyposis • Post endoscopic mucosal resection • HNPCC with any polyps identified at previous colonoscopy • More than 5 polyps at previous colonoscopy

Table 2. Symptomatic patient baseline characteristics and CCE outcomes

Number of patients - n	263
Age (years) – mean (SD)	60.0 (11.05)
Sex	
Male	117 (55.5)
Female	146 (44.5)
BMI (kg/m^2)	
<18.5	2 (0.8)
18.5-24.9	55 (20.9)
25-29.9	83 (31.6)
30-39.9	82 (31.2)
>40	9 (3.4)
Missing	32 (12.2)
eGFR (ml/min)	
>= 90	113 (28.2)
60- 89	64 (16.0)
45-59	7 (1.7)
<30	0
Missing	217 (54.1)
Referral Urgency	
Urgent Suspect Cancer	103 (39.2)
Urgent	79 (30.0)
Routine	81 (30.8)
Referral symptoms[1]	
Change in bowel habit	179 (68.1)
Abdominal pain	106 (40.3)
Rectal bleeding	50 (19.0)
Diarrhoea	52 (13.0)
Constipation	35 (8.7)
Weight loss	23 (5.7)
Microcytic anaemia	5 (1.2)
Other	12 (3.0)
Hb (g/L) – mean (SD); n	140.9 (11.6); 200
FIT (µg/g)[1]	
<10	92 (35.0)
10-399	79 (30.0)
>400	4 (1.5)
Missing	88 (33.5)
Digestive system	
Yes	67 (25.5)
No	196 (74.5)
Endocrine, nutrional or metabolic	
Yes	49 (18.6)
No	214 (81.4)
Antidepressant	
Yes	53 (20.2)
No	210 (79.8)
Beta blocker	
Yes	31 (11.8)

No	232 (88.2)
Opioid/opiate	
Yes	21 (8.0)
No	242 (92.0)
Completion rate - %	72.6
Adequate bowel preparation rate - %	80.2
Successful test - %	66.2
Proportion requiring a further procedure - %	62.4

Values are n (percent) unless otherwise stated.[1] More than 1 symptom could be recorded.
Abbreviations: BMI, body mass index; eGFR, estimate glomerular filtration rate; Hb, haemoglobin; FIT, faecal immunochemical test; SD, standard deviation.

Table 3. Surveillance patient baseline characteristics and CCE outcomes

Number of patients - n	137
Age (years) – mean (SD)	62.7 (10.0)
Sex	
Male	79 (57.7)
Female	58 (42.3)
BMI (kg/m^2)	
<18.5	0 (0)
18.5-24.9	19 (13.9)
25-29.9	33 (24.1)
30-39.9	42 (30.7)
>40	2 (1.5)
Missing	41 (29.9)
Surveillance reason	
Previous polyps	74 (53.6)
Colorectal cancer surgery follow-up	34 (24.6)
Family History	18 (13.0)
Hereditary Non-Polyposis Colorectal cancer gene history	11 (8.0)
Other	1 (0.7)
Bowel resection surgery	
Yes	32 (76.6)
No	105 (23.4)
Digestive system	
Yes	32 (23.4)
No	105 (76.6)
Endocrine, nutrional or metabolic	
Yes	23 (16.8)
No	114 (83.2)
Antidepressant	
Yes	20 (14.6)
No	117 (85.4)
Beta blocker	
Yes	18 (13.1)
No	119 (86.9)
opioid/opiate	
Yes	9 (6.6)
No	128 (93.4)
Completion rate - %	71.5
Adequate bowel preparation rate - %	65.0
Successful test - %	55.5
Proportion requiring a further procedure - %	67.9

Values are n (percent) unless otherwise stated.

Abbreviations: BMI, body mass index; SD, standard deviation.

Table 4. Symptomatic patient factors associated with a successful test, adequate bowel preparation and further procedure requirement

		Univariable analysis			Multivariate Analysis				Multivariate analysis with LASSO variable selection		
Patient Characteristics	**Outcome**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**LASSO Coefficient**	**OR**	**95% CI**	**p-value**
Age	Successful test	0.97	0.95 to 0.99	**0.02**	0.97	0.94 to 0.99	**0.02**	-0.01	0.97	0.95 to 0.99	**0.02**
Age	Adequate bowel preparation	0.97	0.94 to 1.00	0.04	0.97	0.94 to 1.01	0.12	-			
Age	Further procedure	1.04	1.02 to 1.06	<0.001	1.04	1.01 to 1.06	0.01	0.02	1.04	1.02 to 1.06	<0.001
FIT group 10-399 µg/g	Further procedure	2.32	1.23 to 4.48	0.01							

Abbreviations: LASSO, least absolute shrinkage and selection operator; FIT, faecal immunochemical test; OR, Odds ratio; CI, confidence interval.

Table 5. Surveillance patient factors associated with further procedure requirement

		Univariable analysis			Multivariate Analysis				Multivariate analysis with LASSO variable selection		
Patient Characteristics	**Outcome**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**	**LASSO Coefficient**	**OR**	**95% CI**	**p-value**
Surveillance reason - Colorectal cancer surgery follow up	Further procedure	0.29	0.07 to 0.98	0.06	0.12	0.00 to 1.61	0.14	-0.53	0.42	0.18 to 0.97	0.04
Previous bowel resection surgery	Further procedure	0.43	0.19 to 0.98	0.04	2.92	0.28 to 78.1	0.42	-			
Beta blocker medication	Further procedure	0.32	0.11 to 0.88	0.03	0.37	0.12 to 1.14	0.09	-			

Abbreviations: LASSO, least absolute shrinkage and selection operator; OR, Odds ratio; CI, confidence interval.