Clinical assessment to determine the risk of bowel cancer using Symptoms, Age, Mass and Iron deficiency anaemia (SAMI)

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Background: The aim of this study was to identify characteristics with independent predictive value for bowel cancer for use in the clinical assessment of patients attending colorectal outpatient clinics.

Methods: This was a 22-year (1986–2007) retrospective cohort analysis of data collected prospectively from patients who attended colorectal surgical outpatient clinics in Portsmouth. The data set was split randomly into two groups of patients to generate and validate a predictive model. Multivariable logistic regression was used to create and validate a system to predict outcome. Receiver operating characteristic (ROC) curves and Hosmer–Lemeshow test were used to evaluate the model’s predictive capability. The likelihood of bowel cancer was expressed as the odds ratio (OR).

Results: Data from 29,005 patients were analysed. Discrimination of the model for bowel cancer was high in the development (C-statistic 0.87, 95 per cent c.i. 0.85 to 0.88) and validation (C-statistic 0.86, 0.84 to 0.87) groups. The most important co-variables in the final model were: age (OR 3.17–27.10), rectal (OR 31.48) or abdominal (OR 1.83–8.45) mass, iron deficiency anaemia (IDA) (OR 4.42–8.38), rectal bleeding and change in bowel habit in combination (OR 5.37), change in bowel habit without rectal bleeding, with or without abdominal pain (OR 2.12–2.52), and rectal bleeding with no perianal symptoms and without change in bowel habit (OR 2.91). Some 91.5 per cent of bowel cancers presented with these characteristics, 40.4 per cent with a mass and/or IDA. In patients with at least one of these characteristics the overall risk of having cancer was 10.0 (range 6.5–50.4) per cent, compared with 1.1 (0.3–2.3) per cent in patients without them.

Conclusion: A clinical assessment that systematically identifies or excludes four symptom–age combinations, a mass and IDA (SAMI) stratifies patients as having a low and higher risk of having bowel cancer. This could improve patient selection for referral and investigation.

Introduction

Few cases of bowel cancer in the UK are detected in the early stages1 and almost one-third of patients have a delay in diagnosis of more than 6 months, with little evidence of improvement over the past 60 years2. The symptoms of bowel cancer are common3–10. Seven million people have rectal bleeding in the UK each year7, so careful selection of patients for investigation is essential11. In 2009, 30 per cent of the total budget for bowel cancer in the UK was spent on investigation and diagnosis; 93 per cent of this budget went on those who did not have cancer12.

The UK Department of Health has introduced public awareness campaigns13 and general practitioner (GP) referral guidelines14,15 to reduce delay in diagnosis and improve poor survival rates from bowel cancer in the UK16,17. However, these strategies can result in unnecessary worry to many people18, high referral rates to hospital19–21, over-investigation22 and high costs to the healthcare system22,19, with little direct evidence of benefit to those with bowel cancer19.

There is a need to improve the efficiency as well as the effectiveness23 of bowel cancer diagnosis. Some studies on the diagnosis of bowel cancer have focused on the value of its symptoms24,25 and combinations of symptoms26–30, without determining the additional diagnostic value of the characteristics of its symptoms and commonly associated physical signs and secondary effects31,32. This study aimed to determine which of all the common characteristics of...
bowel cancer have independent predictive value and would be most useful in a simple clinical assessment to determine the likelihood of bowel cancer.

**Methods**

This was a retrospective cohort analysis using data collected prospectively over a 22-year period (1986–2007).

**Data collection and modes of diagnosis of bowel cancer**

Data were obtained for all patients referred by their GP to the colorectal surgical outpatient clinics at St Mary's Hospital, Queen Alexandra Hospital and two peripheral hospitals in and near Portsmouth between 1986 and 2007. Data were recorded systematically on a structured pro forma, which included all the variables used in the study. This constituted the clinical record for the hospital notes; a copy was made for transcription to the colorectal database. The patient's history was recorded before the diagnosis of bowel cancer was known. Informed consent for the collection and use of the data was obtained on a form sent to the patient with their outpatient appointment. Patients completed a tick-box questionnaire before consultation, and after checking its accuracy the clinician used this as a basis for the patient's history.

Each symptom, including perianal symptoms as well as a mass in the abdomen or rectum, was recorded on the pro forma as present or absent. A blood test for iron deficiency anaemia (IDA) was done either by the GP or in the clinic and recorded when present on the pro forma. A diagnosis of bowel cancer was made in or soon after the clinic visit by flexible sigmoidoscopy, or with selective use of whole colonic imaging (WCI).

Cancers not diagnosed after the first visit were included if detected within 3 years, mainly by referral back to hospital and local hospital audit. A small number were detected by comparison of the database with the Regional Cancer Registry, which has over 95 per cent ascertainment for bowel cancers. Data recorded at the initial visit were included for these and all patients in the study.

Three specialist consultant colorectal surgeons (56.6 per cent), a GP assistant (12.7 per cent) and a nurse specialist (8.8 per cent) entered most of the data in the study. Other colorectal consultants and surgeons in training entered the rest.

**Missing data**

Data on age and sex were available for all patients. Data on the four symptoms and abdominal and rectal masses were systematically recorded as present or absent on a pro forma, which was used as the principal clinical record for the patient, and thus was considered a reliable and complete source of data for the study.

Presence or absence of IDA may not have been determined at the initial examination if not initiated by the GP. IDA would then be recorded as absent, unless the clinician recorded on the pro forma that a haemoglobin test had been requested; data would be updated in accordance with the test result. The prevalence of all major predictor variables was consistent over the course of the study. Data that were not collected consistently during the study (characteristics of symptoms of change in bowel habit and rectal bleeding) were recorded as present or absent/missing. Data on faecal occult blood (FOB) testing were recorded only when the GP had done the test.

**Inclusion and exclusion criteria**

Data were collected for patients newly referred to a colorectal surgical clinic who underwent sigmoidoscopy and/or WCI. Patients were excluded from the analysis if they had already been diagnosed as having bowel cancer and were subsequently being referred to the colorectal clinic. They were also excluded if no procedure (sigmoidoscopy or WCI) had been performed, usually when there was an obvious diagnosis without the need for invasive investigations.

Multiple episodes in the same patient were assumed to be independent if they were more than 3 years apart. Thus, data from a second referral of patients were excluded if within 3 years of the initial attendance, and included if more than 3 years from the first visit.

**Outcome measure**

Bowel cancer was defined as adenocarcinoma of the colon or rectum. Rectal and sigmoid cancers were defined as distal, and the others as proximal.

**Definitions of predictor variables**

Predictor variables included the three primary symptoms of bowel cancer, perianal symptoms and the two physical signs of bowel cancer: change in bowel habit (C), defined as an increased or decreased frequency of defaecation or a change to looser or harder stools (noted as episodic or persistent); rectal bleeding (B), in large amounts, in the toilet, mixed with the motion or separate, and bright or dark; abdominal pain (A), including abdominal discomfort; anal or perianal symptoms (P), including itching, lumps,
soreness, discomfort and pain; rectal mass, defined as any mass palpable on digital rectal examination; and abdominal mass, whether in the left or right iliac fossa, or elsewhere.

**Notation of symptoms**

A plus sign (+) indicates that the symptom was present, and a minus sign (−) that it was absent; when not designated, all patients with and without the symptom were included. Thus, +B + C included all patients with rectal bleeding and change in bowel habit with or without abdominal pain and with or without perianal symptoms.

**Secondary effects of bowel cancer**

The secondary effects were: IDA, defined as microcytosis and hypochromia with a haemoglobin level below the normal range according to sex; changes in weight, defined as weight loss, no weight loss or weight gain; and change in appetite, defined as normal appetite or loss of appetite.

**Other diagnostic factors**

*Faecal occult blood test*

There was no arrangement for, or use of, FOB testing in the clinic; however, a guaiac FOB test was done occasionally by GPs before referral to the clinic.

*Family history*

Patients with a positive family history of bowel cancer were divided into first- or second-degree relatives.

**Statistical analysis**

All statistical analyses35–37 were conducted using SAS® version 9.2 (SAS Institute, Cary, North Carolina, USA), and all statistical tests assumed a two-tailed α of 0.05. Data were expressed as frequencies and percentages for categorical variables. Continuous variables such as age were transformed into a categorical variable.

χ² and Fisher’s exact tests were used to determine the association between categorical variables.

**Model development**

Each patient was assigned a pseudo-random number, distributed uniformly within the interval between 0 and 1; those with a pseudo-random number of 0-60 or less were assigned to the derivation cohort. Model development was run using multivariable analysis on the training data set. The association between bowel cancer and baseline co-variables was estimated by logistic regression using a combination of forward and backward steps. Using records from the development sample, the final set of predictors was selected via forward stepwise variable selection with \( P \leq 0.050 \) to enter and \( P \leq 0.050 \) to stay33,35–39. Each forward selection step was followed by one or more backward elimination steps. The selection process was terminated if no additional variables could be added at \( P \leq 0.050 \) or if the current model was identical to a previously tested model. The final parsimonious model generated a set of independent predictors by their β regression coefficients.

**Model validation**

The model was validated internally on the remaining patients not used for model development. Calibration was assessed by plotting observed versus expected patients who had bowel cancer rates within prespecified subgroups and across quintiles of predicted risk among patients in the validation sample. The Hosmer–Lemeshow37 goodness-of-fit test statistic was also used for objective assessment of calibration.

Model discrimination refers to the ability of the model to assign higher probabilities of outcome to patients who actually had the outcome than to those who did not. Discrimination was assessed by calculating the C-statistic (the area under the receiver operating characteristic (ROC) curve (AUC)) among patients in the validation sample. Values of 0.7–0.8 represent reasonable discrimination, and values exceeding 0.8 indicate good discrimination37.

The model was also validated using all the data for patients referred to the clinic before 2001 and compared with data for those referred during or after 2001 in the discrimination model.

**Results**

From an initial 30913 new referrals, 1908 were excluded from the analysis, including 329 cancers that had already been diagnosed and 1579 that had neither sigmoidoscopy nor WCI. A total of 29 005 referrals (26 972 patients) satisfied the inclusion criteria for development and validation of the model. Some 6-9 per cent of patients (1878 of 26 972) attended more than once after a minimum interval of 3 years for each attendance34. Two patients had five referrals, six had four, 137 had three, 1733 had two, and 25 094 (93-0 per cent) had one referral. In this large population, 1626 had bowel cancer, including 1563 (96-1 per cent) diagnosed at or soon after first presentation and 63 (3-9 per cent) missed cancers, giving an overall prevalence of 5-6 per cent (Table S1, supporting information).
A total of 27,064 patients presented with at least one of the three primary symptoms: a change in bowel habit (C), rectal bleeding (B) or abdominal pain (A). Of these, 1585 (5.9 per cent) had cancer. Of the 41 cancers presenting without one of the three primary symptoms, 25 (61 per cent) presented with IDA, 11 (27 per cent) with an abdominal mass, three (7 per cent) with a rectal mass and nine (22 per cent) with perianal symptoms. The majority of the patients with bowel cancer were over 55 years of age, with a steep increase in numbers between the age groups of 51–55 and 56–60 years. More men than women had bowel cancer (55–5 versus 44–5 per cent respectively), whereas more women than men were referred to outpatients (56–2 versus 43–8 per cent), resulting in a higher overall risk of cancer in men than in women (7.1 versus 4.4 per cent respectively; P < 0.001) (Table S1, supporting information).

Number of patients and bowel cancers with each candidate predictor variable and the proportion with cancer

The number of patients referred to the hospital outpatient clinic and the number with an outcome of bowel cancer by year of the clinic is shown in Table S2 (supporting information).

Change in bowel habit was the most common symptom in bowel cancer (74–0 per cent), and rectal bleeding in combination with a change in bowel habit was the most common symptom combination: 51–0 per cent of all cancers (829 of 1626) and 72–1 per cent of those presenting with rectal bleeding (Table S1, supporting information). The least common symptom presentation was abdominal pain as a single symptom (61 of 1626, 3–8 per cent). Twice as many patients with cancer had a rectal mass (398 of 1626, 24–5 per cent) compared with those who had an abdominal mass (203 (188 had a single abdominal mass, 14 had 2 abdominal masses and 1 had 3) of 1626, 12.5 per cent), and 156 (9–6 per cent) of patients with cancer had IDA, of whom 131 (84–0 per cent) had one of the three primary symptoms of bowel cancer. The risk of having bowel cancer ranged from 1.7 per cent (+B – C + P) to 21.3 per cent (+B + C – A – P), simply on the basis of symptom combinations (Table S1, supporting information).

Univariable and multivariable analyses

In univariable analysis, in addition to age and sex, most of the 52 candidate predictor variables shown in Table S1 (supporting information) were significantly (P < 0.250) associated with the outcome (Table 1), apart from abdominal pain (odds ratio (OR) 0.94), change in bowel habit without rectal bleeding (OR 0.96), and some of the characteristics of rectal bleeding and change in bowel habit. Of these candidate predictors, 30, including age and sex, were selected as statistically significant or potentially clinically relevant predictors of bowel cancer to establish the final prediction model. Twenty variables including age and sex were retained in the final model (Table 2). After this process, the co-variables were scrutinized by the study team to arrive at the final set of eight risk factors (age, 4 symptom combinations, 2 physical signs and IDA) that could be used in a simple clinical algorithm.

Model performance

In the development data set, there were 17,403 patients (60–0 per cent), including 7651 men (44–0 per cent), of mean(s.d.) age 60–1(16–3) years. The final validation cohort included 11,602 patients (40–0 per cent), including 5043 men (43–5 per cent), aged 60–1(16–5) years. Bowel cancer occurred in 1626 patients, 5–6 per cent of the study population: 990 (5–7 per cent) in the training set and 636 (5–5 per cent) in the validation set.

The model coefficients and ORs with 95 per cent confidence intervals for each co-variable are shown in Table 2. The Hosmer–Lemeshow goodness-of-fit test with ten deciles gave a value of 5.31 (8 d.f., P = 0.724) on the training set and 8.11 (8 d.f., P = 0.430) on the validation set.

There was no significant deviation between the observed and predicted events, suggesting an excellent goodness of fit. Calibration plots were generated using predicted versus observed results. To obtain objective quantification of the degree of calibration, the overall calibration line was compared with a line demonstrating perfect calibration (intercept, 0; slope, 1). There was good agreement between predicted and observed bowel cancer rates (Fig. S1, supporting information). Calibration lines of predicted versus observed results for data before 2001, and those collected during and after 2001 were similar (Fig. S2, supporting information).

Discrimination of the model

The C-statistic was 0.87 (95 per cent c.i. 0.85 to 0.88) on the development set and 0.86 (0.84 to 0.87) on the validation set, as shown in ROC curves (Fig. 1).

There was a sensitivity of 23.9 per cent and specificity of 99.3 per cent when the probability of bowel cancer was over 50 per cent, compared with 38.3 and 97.1 per cent respectively, with a 20 per cent probability. This illustrates that a higher cut-off with a higher probability leads to better specificity, at the price of lower sensitivity.

With regard to performance of the model across time, given that the data were collected for 22 years, the final
### Table 1 Results of the univariable analysis

| Characteristics of rectal bleeding† | Estimate | P     | Odds ratio |
|------------------------------------|----------|-------|------------|
| Bright                             | 0.020    | 0.697 | 1.02 (0.92, 1.13) |
| Dark                               | 0.935    | 0.001 | 2.55 (2.25, 2.88) |
| In toilet                          | 0.327    | 0.001 | 1.39 (1.18, 1.64) |
| Separate                           | 0.049    | 0.559 | 0.95 (0.81, 1.11) |
| Mixed                              | 0.629    | 0.001 | 2.29 (1.80, 2.92) |
| On pants                           | 0.128    | 0.340 | 1.14 (0.87, 1.48) |
| On paper                           | 0.148    | 0.026 | 1.16 (1.02, 1.32) |
| Coating stool                      | 0.441    | 0.001 | 1.55 (1.22, 1.99) |
| Drip                               | 0.354    | 0.012 | 0.70 (0.53, 0.92) |
| Large volume                       | 0.719    | 0.001 | 0.49 (0.32, 0.73) |

| Characteristics of change in bowel habit‡ | Estimate | P     | Odds ratio |
|-------------------------------------------|----------|-------|------------|
| Persistent                                | 0.396    | 0.001 | 1.49 (1.18, 1.87) |
| Episodic                                  | 0.247    | 0.053 | 0.78 (0.61, 1.00) |
| Increased frequency of defaecation       | 0.708    | 0.001 | 2.03 (1.83, 2.25) |
| Decreased frequency or defaecation       | 0.134    | 0.245 | 0.88 (0.70, 1.10) |
| Looser stools                             | 0.834    | 0.001 | 2.30 (2.08, 2.55) |
| Harder stools                             | 0.079    | 0.380 | 1.08 (0.91, 1.29) |

| IDA                                       |          |       |            |
|-------------------------------------------|----------|-------|------------|
| Present                                   | 1.807    | 0.001 | 6.09 (5.04, 7.35) |
| IDA with B, C or A                       | 1.921    | 0.001 | 6.83 (5.55, 8.40) |
| IDA without B, C or A                    | 1.000    | 0.000 | 1.00 (1.00, 1.00) |

| Physical signs                           |          |       |            |
|-------------------------------------------|----------|-------|------------|
| Rectal mass                               | 3.712    | 0.001 | 40.95 (34.36, 48.80) |
| Left iliac mass                           | 2.083    | 0.001 | 8.03 (6.00, 10.75) |
| Right iliac mass                          | 1.709    | 0.001 | 5.52 (4.25, 7.18) |
| Other abdominal mass                      | 0.995    | 0.001 | 2.70 (2.11, 3.47) |

| Other possible diagnostic factors         |          |       |            |
|-------------------------------------------|----------|-------|------------|
| Weight loss§                              | 0.950    | 0.001 | 2.59 (2.31, 2.90) |
| Reduced appetite¶                         | 0.923    | 0.001 | 2.52 (1.95, 3.24) |
| Positive FOB test result                  | 0.372    | 0.066 | 1.45 (0.98, 2.16) |

| Family history                           |          |       |            |
|-------------------------------------------|----------|-------|------------|
| First-degree relative with bowel cancer  | 0.193    | 0.033 | 1.21 (1.02, 1.45) |
| Second-degree relative with bowel cancer  | 0.634    | 0.001 | 0.53 (0.38, 0.73) |

Values in parentheses are 95 per cent confidence intervals. Each subgroup is compared separately with the reference category (odds ratio 1·00); the reference category is all patients when the variable is not present or not seen (0), except where specified. Reference category is †no rectal bleeding, ‡no change in bowel habit, §no weight loss and ¶normal appetite. IDA, iron deficiency anaemia; FOB, faecal occult blood.
Table 2  Multivariable logistic regression analysis for the final model

| Characteristic                        | Odds ratio | P     |
|--------------------------------------|------------|-------|
| Male sex                             | 1.93 (1.68, 2.23) | <0.001|
| Age (years)                          |            |       |
| 46–50                                | 3.17 (1.71, 6.15) | <0.001|
| 51–55                                | 5.56 (2.52, 8.08) | <0.001|
| 56–60                                | 14.25 (6.97, 19.53) | <0.001|
| 61–65                                | 16.53 (7.79, 21.62) | <0.001|
| 66–70                                | 18.06 (9.25, 25.38) | <0.001|
| 71–75                                | 23.29 (10.53, 28.79) | <0.001|
| ≥76                                  | 27.10 (13.95, 37.08) | <0.001|
| Symptom combinations                 |            |       |
| +B + C                               | 5.37 (4.32, 6.63) | <0.001|
| +B − C + P                           | 2.91 (2.23, 3.81) | <0.001|
| +C − B − A                           | 2.12 (1.48, 2.65) | <0.001|
| +C − B + A                           | 2.52 (1.87, 3.19) | <0.001|
| Physical signs                        |            |       |
| Rectal mass                          | 31.48 (24.20, 39.05) | <0.001|
| Right iliac fossa mass               | 8.45 (4.72, 9.84) | <0.001|
| Left iliac fossa mass                | 2.80 (2.26, 3.53) | <0.001|
| Other abdominal mass                 | 1.83 (1.18, 2.47) | <0.003|
| IDA                                  |            |       |
| Present with symptoms                | 4.42 (3.63, 6.61) | <0.001|
| Present with no symptoms             | 8.38 (5.10, 16.05) | <0.001|

Values in parentheses are 95 per cent confidence intervals. Each subgroup is compared separately with the reference category (odds ratio 1.00); the reference category is all patients when the variable is not present or not seen (0), except where specified. Reference category is "no rectal bleeding," no change in bowel habit and no weight loss. B, rectal bleeding; C, change in bowel habit; P, perianal symptoms; A, abdominal pain; IDA, iron deficiency anaemia.

The model was validated not only on the validation set, but also on split data to examine how it performed on data before 2001 and after 2000. The performance and calibration of the model did not differ: AUC 0.86 (95 per cent c.i. 0.84 to 0.87) for validation set; AUC 0.86 (0.85 to 0.88) for examination before 2001; AUC 0.86 (0.85 to 0.88) for examination after 2000.

Independent predictors of bowel cancer

Of the 20 independent predictors of bowel cancer shown in Table 2, the most important were age (OR 3.17–27.10), rectal mass (OR 31.48), abdominal mass varying according to site (OR 8.45–1.83), IDA with (OR 4.42) or without (OR 8.38) symptoms, four symptom combinations +B + C (OR 5.37), +B − C + P (OR 2.91), +C − B + A (OR 2.52) and +C − B − A (OR 2.12), dark red rectal bleeding (OR 2.05) and male sex (OR 1.93). The four negative independent predictors were an episodic change in bowel habit (OR 0.60), a change to harder stools (OR 0.54) and rectal bleeding described as large volume (OR 0.39) or dripping (OR 0.61). The predictive and diagnostic values of various combinations of the eight most important co-variables were determined to outline how they might be used in a simple clinical assessment to risk-stratify patients for appropriate management strategies.

Typical changes in bowel habit and their diagnostic value

Changes to an increased frequency of defaecation and looser stools were more common in patients with cancer than decreased frequency and harder stools (Table S1, supporting information). Only a change to harder stools was retained in the final model as a negative predictor (OR 0.54) (Table 2).

Changes in both frequency and consistency were determined in 614 patients with cancer. Some 558 (90.9 per cent) of these patients presented with a change to an increased frequency and/or to looser stools; 504 (82.1 per cent) presented with both characteristics, 41 (6.7 per cent) with a change to decreased frequency and harder stools or ‘typical’ constipation, and ten (1.6 per cent) with both...
increased and decreased frequency and looser and harder stools.

Diagnostic value of the characteristics of rectal bleeding

Table S1 (supporting information) shows that 31.3 per cent of patients with cancer had dark red rectal bleeding, and this characteristic was retained in the final model (OR 2.05) (Table 2). Although ‘blood mixed with the stool’ had an OR of 2.29 in univariable analysis (Table 1), this co-variable was not retained in the final model. The other characteristics of rectal bleeding had less diagnostic value in univariable analysis (Table 1), and of those selected for multivariable analysis the four retained in the final model had ORs ranging from 1.84 to 0.39 (Table 2).

Diagnostic value of weight loss and reduction in appetite

Table S1 (supporting information) shows that 13.5 per cent of all patients, compared with 27.2 per cent of those with cancer, had weight loss. All patients with cancer and weight loss also had at least one of the primary symptoms and/or a mass or IDA; some 59.6 per cent had abdominal pain. Weight loss was retained in the final model (OR 1.66) (Table 2).

The 7.9 per cent of patients with a reduced appetite (559 of 7054) had a 12.7 per cent risk of having bowel cancer (Table S1, supporting information). Although reduced appetite had an OR of 2.52 in univariable analysis (Table 1), this factor was not retained in the final model.

Forty-nine (69 per cent) of the 71 patients with cancer and a reduction in appetite also had abdominal pain, and 55 (77 per cent) had weight loss. Patients with abdominal pain who also had a reduced appetite and weight loss had a significantly increased risk of bowel cancer compared with those who had abdominal pain without these characteristics: 15.7 per cent (39 of 249) versus 4.2 per cent (106 of 2522) (P<0.001).

Prevalence and symptoms of partial intestinal obstruction

Since 1997, 4.1 per cent of patients with cancer initially referred to outpatients (49 of 1195) were subsequently re-referred as an emergency and had emergency surgery for intestinal obstruction. Forty of these 49 patients (82 per cent) presented to the clinic with abdominal pain, and 28 (57 per cent) also had weight loss, compared with 27.2 per cent of all patients with cancer.

Diagnostic value of a positive family history and faecal occult blood test result

Although a positive family history of bowel cancer in a first-degree relative had significant diagnostic value in univariable analysis (OR 1.21, 95 per cent c.i. 1.02 to 1.45) (Table 1), this factor was not retained in the final model.

Some 7.9 per cent of patients (27 of 342) with a positive FOB result had cancer, but this was not significant in univariable analysis (OR 1.45, 95 per cent c.i. 0.98 to 2.16) (Table 1).

Associations between symptom combinations, masses, iron deficiency anaemia, and cancers proximal to the sigmoid

A total of 27 064 patients, including 1585 with bowel cancer, presented with one of six symptom combinations (Table 3).

A change in bowel habit with rectal bleeding (+C+B) occurred in 52.3 per cent of patients with cancer – the most common presenting symptom combination. Only 5.5 per cent of these cancers were proximal to the sigmoid colon. Abdominal pain as a single symptom was the least common symptom combination, occurring in 61 (3.8 per cent) of all patients with cancer, of whom 44 (72 per cent) had tumours proximal to the sigmoid colon.

Some 40.4 per cent of patients with cancer (640 of 1585) also had an abdominal and/or rectal mass and/or IDA, ranging, according to the symptom combination, from 28.6 per cent (+B−C−P) to 61 per cent (+A−B−C).

Overall, 258 (16.3 per cent) of all symptomatic cancers were proximal to the sigmoid colon. The symptom combinations most commonly associated with proximal cancer (+C−B+A and +A−B−C) also had the highest proportion of cancers with an abdominal mass or IDA (Table 3).

Risk stratification according to combinations of the main co-variables for use in a simple clinical algorithm (SAMI)

Table 4 shows the overall risk of having bowel cancer in patients presenting with one of ten age–symptom combinations of bowel cancer and how the risk varies in various subgroups of these patients according to four other co-variables included in the final model: an abdominal or rectal mass, IDA and sex.

Some 91.5 per cent of bowel cancers (1450 of 1585) presented with at least one of the main co-variables identified by the model, 1339 with one of three higher-risk age–symptom combinations and 111 with a mass and/or IDA in cancers not presenting with these age–symptom combinations. The overall risk of having cancer when
Table 3 Associations between the symptom combinations of bowel cancer and an abdominal or rectal mass and iron deficiency anaemia, and the proportion with cancer proximal to the sigmoid colon

| Symptom combinations | +C + B* | +C – B – A* | +C – B + A* | +B – C – P* | +B – C + P | +A – B – C | Total |
|----------------------|---------|-------------|-------------|-------------|------------|------------|-------|
| No. of patients      | 7944    | 2830        | 4087        | 3077        | 7397       | 1729       | 27064 |
| No. of cancers       | 829 (52-3) | 146 (9-2) | 229 (14-4) | 196 (12-4) | 124 (7-8) | 61 (3-8) | 1585 (100) |
| Proportion with cancer proximal to sigmoid colon | 46 (5-5) | 27 (18-5) | 96 (41-9) | 30 (15-3) | 151 (12-1) | 44 (72) | 258 (16-3) |
| Proportion of cancers with a rectal mass | 251 (30-3) | 39 (26-7) | 27 (11-8) | 35 (17-9) | 39 (31-5) | 4 (7) | 395 (24-9) |
| Proportion of cancers with an abdominal mass | 55 (6-6) | 19 (13-0) | 67 (29-3) | 15 (7-7) | 7 (5-6) | 29 (48) | 192 (12-1) |
| Proportion of cancers with IDA | 41 (4-9) | 16 (11-0) | 40 (17-5) | 13 (6-6) | 11 (6-9) | 10 (16) | 131 (8-3) |
| Proportion of cancers with a mass and/or IDA | 317 (38-2) | 69 (47-3) | 111 (48-5) | 56 (28-6) | 50 (40-3) | 37 (61) | 640 (40-4) |

Values in parentheses are percentages. *The four symptom combinations identified by the model as having independent predictive value. †Site unknown for one cancer. C, change in bowel habit; B, rectal bleeding; A, abdominal pain; P, perianal symptoms; IDA, iron deficiency anaemia. +C + B, change in bowel habit with rectal bleeding with or without abdominal pain; +C – B – A, change in bowel habit with no rectal bleeding or abdominal pain; +C – B + A, change in bowel habit without rectal bleeding but with abdominal pain; +B – C – P, rectal bleeding with no change in bowel habit and no perianal symptoms, with or without abdominal pain; +B – C + P, rectal bleeding with no change in bowel habit but with perianal symptoms, with or without abdominal pain; +A – B – C, abdominal pain as a single symptom with no rectal bleeding or change in bowel habit.

Table 4 Risk stratification for bowel cancer according to various combinations of the main co-variables identified by the model for use in a simple clinical algorithm: age–symptom combinations, a mass and/or iron deficiency anaemia, and the effect of sex

| Symptom combinations of bowel cancer | +C + B† | +C – B† | +B – C – P† | +B – C + P† | +A – B – C |
|------------------------------------|---------|---------|-------------|-------------|------------|
| Age (years)                        | ≥ 40    | < 40    | ≥ 60        | < 60        | ≥ 60       | < 60      |
| No. of patients                    | 6989    | 955     | 5194        | 1723        | 1397       | 2705      | 4692    | 1077    | 652 |
| No. of cancers                     | 823*    | 6       | 338*        | 57          | 178*       | 18        | 97      | 27      | 53   | 8 |
| Overall risk of bowel cancer (%)   | 11.8    | 0.6     | 6.6         | 2.1         | 10.6       | 1.3       | 3.6     | 0.6     | 4.9  | 1.2 |
| Risk with mass and/or IDA (%)      | 50.4    | 8.6 (2*) | 31.5        | 16.3 (16*)  | 38.1       | 13.5 (5*) | 26.8 (40*) | 11.0 (10*) | 21.8 (32*) | 12.8 (5*) |
| Risk with no mass or IDA (%)       | 8.0     | 0.3 (0.1) | 3.7         | 1.3 (2.1)   | 8.2        | 1.0 (1.31) | 2.2 (5.71) | 0.4 (1.71) | 2.3 (21.1) | 0.5 (31) |
| Risk in men with no mass or IDA (%)| 11.6    | 0.0     | 6.4         | 2.2         | 8.7        | 1.2       | 2.0     | 0.5     | 4.0  | 0.5 |
| Risk in women with no mass or IDA (%)| 5.5    | 0.5     | 2.1         | 0.8         | 7.8        | 0.7       | 2.4     | 0.2     | 1.3  | 0.5 |

*Numbers of cancers with one of the higher age–symptom combinations with independent predictive value, or with a mass or iron deficiency anaemia (IDA) (n = 1450); †Numbers of cancers presenting without these characteristics (n = 135). ‡Includes patients with and without abdominal pain. +C + B, change in bowel habit with rectal bleeding; +C – B, change in bowel habit with no rectal bleeding; +B – C – P, rectal bleeding with no perianal symptoms and no change in bowel habit; +B – C + P, rectal bleeding with perianal symptoms but no change in bowel habit; +A – B – C, abdominal pain as a single symptom with no rectal bleeding or change in bowel habit.

Presenting with these characteristics was 10.0 per cent (1450 of 14,459), ranging from 6.5 (338 of 5194) to 50.4 (314 of 623) per cent. The overall risk of having cancer in 135 patients with bowel cancer presenting with low-risk age–symptom combinations without a mass or IDA was 1.1 per cent (135 of 12,605), ranging from 0.0 (3 of 920) to 2.3 (21 of 930) per cent.

Table 4 also shows that, although the overall risk of having bowel cancer in patients aged 40 years or more presenting with +C + B was 11.8 per cent, it varied from 50.4 per cent (314 of 623) in the subgroup of patients with a mass and/or IDA to 5.5 per cent (208 of 3781) in women presenting without a mass or IDA. Similarly, in patients aged 60 years or over presenting with +C – B, the overall risk of having cancer was 6.5 per cent (338 of 5194), but this decreased to 2.1 per cent (61 of 2896) in women with no mass or IDA.

Whereas there was a reduction in the risk of having cancer in women compared with men presenting with a change in bowel habit, there was little or no sex effect in patients presenting with rectal bleeding without a change in bowel habit (Table 4).

Further risk stratification of patients with low-risk age–symptom combinations with no mass or anaemia

Of the 135 patients with cancer presenting with low-risk age–symptom and sign combinations, 32 had either dark red bleeding or weight loss, also independent predictors of bowel cancer. However, there was only a small further reduction in the overall risk of having cancer in patients with neither of these two characteristics: 0.9 per cent (103 of 12,026). Of these 103 cancers presenting with low-risk symptoms and signs, 83 (68.6 per cent) were in the sigmoid colon or rectum, and five of the remaining 20 proximal cancers showed an adenomatous polyp on flexible sigmoidoscopy. Thus 15 proximal cancers presented with no mandatory reason for WCI during the 22 years of the study.
Discussion

The primary aim of this study was to develop and test a model to predict the likelihood of having bowel cancer based on clinical presentation, clinical examination, and the presence or absence of anaemia. Some 91.5 per cent of patients with bowel cancer presented with at least one of eight co-variables in the final model, and the overall risk of having cancer in patients presenting with these characteristics was 10.0 (range 6.5–50.4) per cent, compared with 1.1 (0.3–2.3) per cent in those without. Overall, 40.4 per cent of patients presented with a mass (OR 2.80–31.48) and/or IDA (OR 4.42–8.38), emphasizing the high prevalence and importance of these characteristics in diagnosing bowel cancer. Some 51.9 per cent of cancers occurred in patients aged 40 years or over with rectal bleeding in combination with a change in bowel habit, and a further 32.6 per cent in patients aged 60 years or more presenting with a change in bowel habit with no rectal bleeding with or without abdominal pain, or rectal bleeding without anal symptoms. This means that almost one-third of bowel cancers presented with at least two characteristics with independent predictive value.

It is also important to note that in 90.9 per cent of cancers presenting with a change in bowel habit this was an increased frequency of defaecation and/or looser stools. This was the most common presenting symptom of bowel cancer amounting to 67.3 per cent of all cancers referred to outpatients. Very few cancers presented with constipation evidenced by hard stools (a negative predictor) and reduced frequency of defaecation, or with alternating constipation and diarrhoea. An episodic change in bowel habit was also an independent predictor of low risk, which means that ‘treat, watch and wait’ diagnostic strategies are essential to establish that a change in bowel habit is persistent and unremitting.

These findings emphasize the importance of defining a change in bowel habit in terms of its persistency, consistency and frequency, rather than as constipation or diarrhoea, which have no or little diagnostic value in primary care.

In this study, 96.1 per cent of bowel cancers were diagnosed at or soon after the first outpatient visit. Only data from the first visit for the 3.9 per cent ‘missed’ cancers, subsequently diagnosed over the next 3 years, were used for the analysis.

The findings of this study suggest that a simple, but structured, clinical assessment that systematically identifies or excludes eight of the co-variables in the final model can distinguish groups of patients with a risk of having cancer ranging from 0.3 to 50.4 per cent (Table 4). This table also shows that only three age–symptom combinations in patients without a mass or IDA are likely to meet the 3 per cent threshold set for urgent referral in the new National Institute for Health and Care Excellence (NICE) GP referral guidelines.

Using more of the 20 co-variables identified by the model could refine risk stratification further, but this may be of little additional clinical value and would require online decision support. However, an online bowel symptom checker for people in the community based on these findings is on the NHS Choices website, and currently has between 33 000 and 45 000 hits per month, making it one of the most popular symptom checkers on the NHS Choices website.

Although abdominal pain had little diagnostic value, there is a threefold increase in the risk of having cancer when it is associated with weight loss and loss of appetite. Abdominal pain also occurred more frequently in patients with cancer who were subsequently re-referred with full intestinal obstruction. When associated with weight loss, abdominal pain is now included for bowel cancer in the NICE GP referral guidelines.

Several characteristics of rectal bleeding had independent predictive value but most, apart from dark red bleeding (OR 2.05) had little additional diagnostic value. Although blood mixed with the stool had an OR of 2.29 in univariable analysis, it did not have independent predictive value.

Weight loss has been shown to have diagnostic value in primary care. In the present study, it never occurred without a symptom, mass or IDA, suggesting that weight loss per se is an uncommon presentation of bowel cancer, and that emphasizing weight loss in public awareness campaigns and guidelines may do more harm than good.

FOB testing and a family history of bowel cancer had no additional diagnostic value. However, more structured use of FOB or faecal immunochemical testing, and identifying the age of the relative when taking a family history, could increase their diagnostic value.

Although these findings could result in more reliable risk stratification, the management of patients at ‘low but not no risk’ of having bowel cancer remains a major challenge. Patients need to understand the benefits of ‘treat, watch and wait’ diagnostic strategies, and doctors the importance of safety netting. Primary care doctors in the UK, who on average see only one patient with bowel cancer a year, will encounter a patient with none of the typical characteristics once every 10 years. Some of these cancers will be in groups of patients with an overall risk of less than one in 300, the risk of bowel cancer in older people with no symptoms.

This study, once again, shows that relatively small numbers of cancers proximal to the sigmoid colon are referred...
to outpatients, and most that are referred have a mass or IDA. This means that after a normal finding on flexible sigmoidoscopy, careful selection for WCI is required to avoid overinvestigation. The strength of this study is that it is based on data collected prospectively in a structured way before the patient or clinician knew the diagnosis. The limitation of the study is the uncertainty about the completeness of data collection and that some variables were not collected throughout the study. However, in view of the size of the data set, it is likely that missing data will not greatly affect the overall conclusions of the study.

Although three consultants saw 57 per cent of patients, trainees (6 per cent), a GP (13 per cent) and a specialist endoscopy nurse (9 per cent) also saw patients, and this could have increased the risk of a different interpretation of some of the less clearly defined variables. It is possible that these findings will not be generalizable, but 80 per cent of patients with bowel cancer are referred to surgical clinics and those referred to medical clinics have been shown to have similar presentations. External studies on the added diagnostic value of symptom combinations compared with single symptoms support the present findings, but further studies are needed on the predictive value of symptoms with and without a mass or IDA, and the diagnostic values of the characteristics of a change in bowel habit.

A simple, but structured, clinical assessment that systematically identifies or excludes a symptom–age combination, a mass and IDA (SAMI) can broadly stratify patients into those at low risk as well as those at higher risk of having bowel cancer. Greater risk stratification could be achieved by using all the co-variables identified by the final model, and the diagnostic values of the characteristics of a change in bowel habit.

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**Supporting information**

Additional supporting information may be found in the online version of this article:

**Table S1** Data on all patient referrals and those with bowel cancer for each variable used in the analysis, and the proportion with cancer (Word document)

**Table S2** Number and outcome of patients referred to outpatient clinic by year (Word document)

**Fig. S1** Calibration plot of validation data set (Word document)

**Fig. S2** Calibration plot of data for patients examined before 2001 and after 2000 (Word document)

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