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Computed tomographic colonography versus barium enema for diagnosis of colorectal cancer or large polyps in symptomatic patients (SIGGAR): a multicentre randomised trial

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Summary

Background

Barium enema (BE) is widely available for diagnosis of colorectal cancer despite concerns about its accuracy and acceptability. Computed tomographic colonography (CTC) might be a more sensitive and acceptable alternative. We aimed to compare CTC and BE for diagnosis of colorectal cancer or large polyps in symptomatic patients in clinical practice.

Methods

This pragmatic multicentre randomised trial recruited patients with symptoms suggestive of colorectal cancer from 21 UK hospitals. Eligible patients were aged 55 years or older and regarded by their referring clinician as suitable for radiological investigation of the colon. Patients were randomly assigned (2:1) to BE or CTC by computer-generated random numbers, in blocks of six, stratified by trial centre and sex. We analysed the primary outcome—diagnosis of colorectal cancer or large (≥10 mm) polyps—by intention to

The trial is an International Standard Randomised Controlled Trial, number 95152621.

3838 patients were randomly assigned to receive either BE (n=2553) or CTC (n=1285). 34 patients withdrew consent, leaving for analysis 2527 assigned to BE and 1277 assigned to CTC. The detection rate of colorectal cancer or large polyps was significantly higher in patients assigned to CTC than in those assigned to BE (93 [7·3%] of 1277 *vs* 141 [5·6%] of 2527, relative risk 1·31, 95% CI 1·01–1·68; p=0·0390). CTC missed three of 45 colorectal cancers and BE missed 12 of 85. The rate of additional colonic investigation was higher after CTC than after BE (283 [23·5%] of 1206 CTC patients had additional investigation *vs* 422 [18·3%] of 2300 BE patients; p=0·0003), due mainly to a higher polyp detection rate. Serious adverse events were rare.

Interpretation

CTC is a more sensitive test than BE. Our results suggest that CTC should be the preferred radiological test for patients with symptoms suggestive of colorectal cancer.

Funding

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Introduction

Several procedures are available to investigate patients with symptoms suggestive of colorectal cancer. Barium enema (BE) is the most long-established method and, despite concerns about its sensitivity,[1] figures from the UK Department of Health show that more than 70 000 BE examinations were undertaken in 2011 in England alone.[2]

Computed tomographic colonography (CTC), or virtual colonoscopy, is a relatively new radiological technique for imaging the large bowel. It has received much attention as a screening test[3, 4, 5, 6] and has also been recommended for investigation of patients with symptoms suggestive of colorectal cancer.[7, 8, 9] CTC is thought to have higher sensitivity than BE and studies have shown that patients prefer it to BE.[10, 11, 12] However, no randomised trials have been undertaken to guide health policy on whether CTC should replace BE.

We have undertaken two pragmatic multicentre randomised trials: one comparing CTC with BE, and another comparing CTC with colonoscopy. We chose this approach because most clinicians do not regard

BE and colonoscopy as comparable tests, so one trial with three-way randomisation between the procedures would be impractical.

We report here results of the trial comparing CTC with BE for diagnosis of colorectal cancer or large (≥10 mm) polyps in symptomatic patients for whom the referring clinician preferred a radiological examination. The parallel trial comparing CTC with colonoscopy,[13] and our studies of patient acceptability[14, 15] and cost-effectiveness,[16] are reported elsewhere.

Methods

Study design and participants

The design and rationale of this multicentre randomised trial have been published previously.[17] The trial protocol can be found online. Research nurses at 21 UK National Health Service (NHS) teaching and general hospitals recruited patients referred by their family doctor for investigation of symptoms suggestive of colorectal cancer. Patients were eligible if they were aged 55 years or older, were fit to undergo full bowel preparation, had no known genetic predisposition to cancer, had no history of inflammatory bowel disease, had not had a whole-colon examination in the past 6 months, and were not in active follow-up for previous colorectal cancer. We obtained demographic and baseline clinical data such as age, sex, and symptoms for all potentially eligible patients. The consulting clinician then decided in line with usual practice whether to investigate the patient using colonoscopy or BE (the default examinations). We created two parallel trials and, within each, patients were randomly assigned to the default examination or CTC.[17] No patients were enrolled in both trials.

We obtained ethical approval from the Northern and Yorkshire Multicentre Research Ethics Committee and from all participating hospitals. The trials were supervised by independent data monitoring and trial steering committees. All patients gave informed written consent.

Randomisation

We randomly allocated patients (2:1) to receive either BE or CTC. A statistician (RE) generated the randomisation codes at a remote site, and codes were kept concealed until interventions were assigned. RE was involved in the design of both the trial and its database, but had no involvement in data collection or interpretation. Randomisation was done centrally by computer random number generation, in blocks of six, stratified by centre and patient sex. Participants and those administering the procedures were not

] to the assigned study intervention.

Procedures

Double-contrast BE was undertaken after full bowel preparation and administration of an intravenous spasmolytic, with carbon dioxide or air for insufflation. Digital fluoroscopic images of the double-contrasted colorectum were obtained to the caecum, supplemented by overcouch decubitus films.

Methods for CTC were in accordance with the contemporary consensus on best practice,[18] including full bowel preparation and gas insufflation. Multidetector-row scanners (minimum four rows) were used with a maximum detector collimation of 2·5 mm and a pitch that allowed abdominal coverage (40 cm) within one breath-hold (20 s). Prone and supine scans were recommended. Readers used two-dimensional (2D) and three-dimensional (3D) visualisation as needed, but a minimum requirement was a primary 2D analysis with volume or surface rendering for problem solving. The reading platform was decided according to local preference, as was use of intravenous contrast and faecal tagging. Computer-assisted detection was available.

82 practitioners (radiologists or fully-trained radiographic technicians) interpreted the BE studies. All reports were either written or verified by a radiologist, except in one centre where dual reporting by senior radiographers was standard practice. 39 radiologists (including 35 from the parallel trial of CTC *vs* colonoscopy[13]) interpreted the CTC studies. All readers of CTC were familiar with interpreting the procedure, and those who had read fewer than 100 cases, or who desired additional training, attended a supplementary 2 day course. The radiologists and radiographers issued a report as usual and completed a case report form. Flexible sigmoidoscopy (FS) was undertaken before the randomised procedure in some hospitals. Details of these FS examinations were recorded, including any lesions seen.

Adverse events within 24 h of the randomised procedure were recorded on the case report form, or on a questionnaire completed by patients the following morning. Details of unplanned hospital admissions within 30 days were collected by manually searching hospitals' patient administration systems.

Referrals for additional tests after the randomised procedure were made at the discretion of local clinicians, and research nurses collected the reports from these procedures.

Outcomes

The primary outcome was the detection rate of colorectal cancer or large (≥10 mm) polyps, confirmed histologically when possible. Secondary outcomes were miss rates for colorectal cancer, referral rates for additional colonic investigation, extracolonic cancer diagnoses, all-cause mortality, and serious adverse events. We also analysed extracolonic findings at CTC.

Our definition of colorectal cancer included all cancers with International Statistical Classification of Diseases and Related Health Problems, revision 10 (ICD-10) site codes C18–C20. Polyp size was defined as the largest measurement at endoscopy, histology, or surgery. Details of cancer diagnoses (colonic and extracolonic) and deaths in the trial cohort were obtained from the NHS Information Centre (NHSIC). A colorectal cancer was defined as missed if it was identified through NHSIC as occurring within 36 months of randomisation, but was not detected by the randomised procedure or mentioned in the patient's discharge letter.

We defined additional colonic investigation as any subsequent examination of the colon until diagnosis (usually histological confirmation of a cancer or polyp), or until a patient was referred back to their family doctor.

Extracolonic cancers included all reported primary malignant neoplasms, excluding colorectal cancers (C18–C20) and non-melanoma malignant neoplasms of the skin (C44).

A serious adverse event was defined as any incident causing hospital admission, death, threat to life, or permanent impairment.[19] An expert panel consisting of a radiologist, a gastroenterologist, and a colorectal surgeon reviewed reasons for unplanned hospital admissions and deaths within 30 days to decide whether any were attributable to a randomly assigned procedure (reviewers were masked to the assigned procedure). Panel members assessed cases independently and a consensus was reached when any disagreement arose.

Patients with extracolonic findings at CTC were followed up until either a diagnosis was given, the patient was put into regular surveillance, or a decision was made not to investigate further. The expert panel reviewed diagnoses resulting from extracolonic findings at CTC to establish whether these diagnoses could have explained patients' presenting symptoms.

Statistical analysis

We estimated that a sample size of 3402 would give 80% power to detect a significant difference in detection rates of colorectal cancer or large polyps at α=0·05 (two-tailed), assuming a diagnostic yield of 5% for BE and 7·5% for CTC, and with randomisation in a 2:1 ratio in favour of BE.[17] The primary outcome was analysed both by intention to treat and in only those patients who had their randomised procedure (excluding lesions seen at previous FS). All secondary outcomes were analysed only in patients who had their randomised procedure, except for extracolonic cancers and overall mortality, which were analysed by intention to treat. The analysis of detection rates was per patient, using the most advanced colonic lesion

sed.

We analysed all extracolonic cancers diagnosed within 36 months of randomisation, and calculated expected numbers by applying age-sex-specific cancer incidence for the general population to our cohort, having adjusted for reported mortality.[20] We compared incidence assuming a Poisson distribution.

Categorical outcomes were compared using Pearson's χ^2 test or Fisher's exact test, as appropriate. We calculated relative risks (RRs) or risk differences with 95% CIs. We showed RRs for the primary outcome by age group (<65 years and ≥65 years) and sex using forest plots, and used tests of interaction (Mantel-Haenszel) to identify significant differences. To check whether clustering by trial centre affected results, we also analysed the primary outcome using random effects logistic models allowing for heterogeneity in the outcome and intervention effects by centre (odds ratios were compared).[21] All tests were two-tailed with significance assigned at 5%. We analysed the data using Stata 10.1

The trial is an International Standard Randomised Controlled Trial, number 95152621.

Role of the funding source

The primary funder (the National Institute for Health Research) stipulated a randomised controlled design, but no funders or providers of equipment were involved in the collection, analysis, or interpretation of data, nor in the writing or submitting of the report. SH, KW, ED, IK-H, and WA had full access to the study data, whereas CvW, GY, RJL, and JW had access to subsets of the data. All authors take responsibility for the decision to submit for publication.

Results

Recruitment for both trials began in March, 2004, and was completed in December, 2007. Of 8484 potentially eligible patients, 3036 were not included because either they or their clinician declined consent (for specific reasons, see appendix) and 1610 entered the accompanying CTC versus colonoscopy trial.[13] Of the remaining 3838 patients who entered the CTC versus BE trial, 34 subsequently withdrew consent (26 [1·0%] in the BE group and eight [0·6%] in the CTC group), leaving 3804 for analysis (2527 assigned to BE and 1277 to CTC; figure 1).

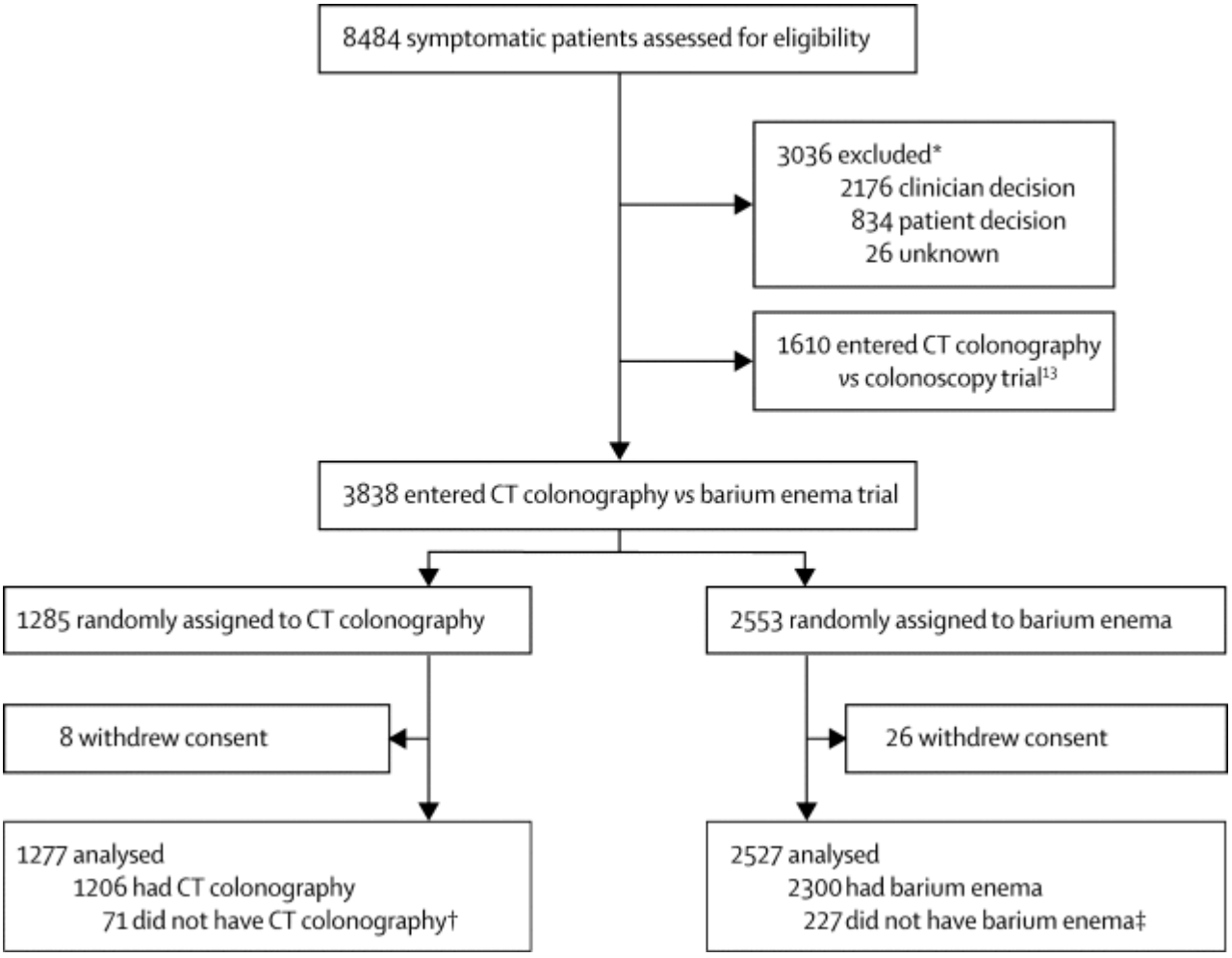

Figure 1 Trial profile

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The median age of participants in this trial was 69 years (IQR 62–75) and 2331 (61%) were women. The most frequent presenting symptoms were change in bowel habit, abdominal pain, and rectal bleeding (table 1). Participants included in this trial were more likely to be female, younger, and to present with abdominal pain or a change in bowel habit than were excluded patients. They were less likely to present with rectal bleeding, anaemia, or weight loss (table 1).

Table 1 Characteristics of patients included in this trial versus excluded patients

			Patients included in CT colonography *vs* barium enema trial		Comparison of included patients	
			CT colonography (n=1277)	Barium enema (n=2527)	Patients included in CT colonography *vs* barium enema trial (n=3804)	Exclu patie (n=3(
Sex						
	Male		490 (38%)	983 (39%)	1473 (39%)	1251 (41%
	Female		787 (62%)	1544 (61%)	2331 (61%)	1785 (59%
Age (years)						
	55–64		416 (33%)	826 (33%)	1242 (33%)	802 (:

Data are number (%) unless otherwise specified.

*** Patients excluded from both this trial and the parallel CT colonography versus colonoscopy trial.**

† Some patients reported more than one symptom.

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A lower proportion of patients assigned to BE than to CTC had their assigned procedure (2300 [91·0%] of 2527 *vs* 1206 [94·4%] of 1277; p=0·0002). Reasons why patients did not have the procedure are outlined in the appendix. Of those patients who did not have the assigned procedure, 85 (37%) of 227 in the BE group (27%) of 71 in the CTC group had an alternative whole-colon examination (figure 1).

FS was undertaken before the scheduled randomised procedure in 199 (7·9%) patients in the BE group and 89 (7·0%) in the CTC group (p=0·32). Having FS did not affect whether the patient subsequently had their randomised procedure (263 [91·3%] of 288 patients with previous FS *vs* 3243 [92·2%] of 3516 patients without FS had their randomised procedure; p=0·58).

Of 2527 patients assigned to BE, 141 (5·6%) were diagnosed with colorectal cancer or a large polyp: 119 (4·7%) at BE, 16 (0·6%) at previous FS, and six (0·2%) after an alternative procedure. By comparison, 93 (7·3%) of 1277 patients assigned to CTC had colorectal cancer or a large polyp diagnosed: 85 (6·7%) at CTC, six (0·5%) at previous FS, and two (0·2%) after an alternative procedure (see footnote to table 2 for histological diagnoses of cancers and large polyps). The detection rate of colorectal cancer or large polyps was significantly higher in the CTC group than in the BE group (RR 1·31, 95% CI 1·01–1·68; p=0·0390; table 2), due mainly to a higher detection rate of large polyps (p=0·0098). Detection rates of colorectal cancer did not differ significantly between groups (p=0·66). Analysis of only patients who had their randomised procedure, with exclusion of lesions seen at previous FS, showed that colorectal cancer or large polyps were detected significantly more frequently in those who had CTC than in those who had BE (p=0·0243; table 2). Models controlling for clustering by trial centre showed no attenuation of effect (data not shown).

Table 2 Detection rates of colorectal cancer and large polyps

			CT colonography	Barium enema	Relative risk (95% CI)	p value
All patients, n			1277	2527		
	Colorectal cancer or polyp ≥10 mm		93 (7·3%)	141 (5·6%)	1·31 (1·01–1·68)	0·0390
		Colorectal cancer	47[*] (3·7%)	86[†] (3·4%)	1·08 (0·76–1·53)	0·66
		Polyp ≥10 mm	46[‡] (3·6%)	55[§] (2·2%)	1·66 (1·13–2·43)	0·0098
Patients who had their randomised procedure, n[¶]			1206	2300		
	Colorectal cancer or polyp ≥10 mm		85 (7·0%)	119 (5·2%)	1·36 (1·04–1·78)	0·0243

Data are number, or number (%), unless otherwise specified. Only the most advanced lesion per patient is presented.

*** 45 adenocarcinomas and two cancers that were not histologically confirmed.**

† 80 adenocarcinomas, one carcinoid tumour, and five cancers that were not histologically confirmed.

‡ 41 adenomas, one serrated adenoma, one hyperplastic polyp, and three polyps excised but not retrieved.

§ 51 adenomas, two hyperplastic polyps, one juvenile polyp, and one polyp excised but not retrieved.

¶ Excludes lesions detected previously by flexible sigmoidoscopy.

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Relative detection rates differed significantly by age (p=0·0159): in younger patients (<65 years), the detection rate after CTC was double that for BE, whereas in older patients (≥65 years) the rates were similar (figure 2). This difference might have arisen because lesions in younger patients were smaller (<65 years, median size 25 mm [IQR 12–40]; ≥65 years, 30 mm [15–50]) and CTC was more sensitive than was BE for the detection of smaller lesions (data not shown). Relative detection rates did not differ between men and women (p=0·66; figure 2).

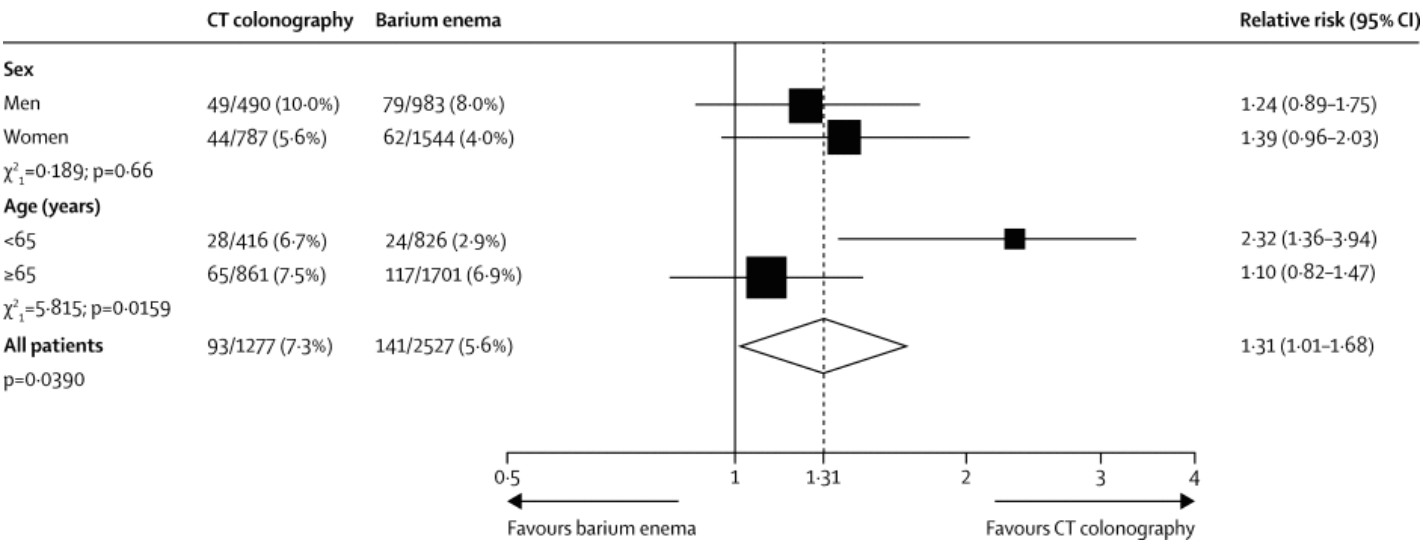

Figure 2 Detection of colorectal cancer or large (≥10mm) polyps by sex and age group

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A higher proportion of patients who had CTC underwent additional colonic investigation than did those who had BE (23·5% *vs* 18·3%; p=0·0003; table 3), with higher rates of additional investigation for suspected cancers or polyps of 10 mm or larger (11·0% *vs* 7·5%; p=0·0005), or for suspected smaller polyps (7·2% *vs* 2·3%; p<0·0001). Conversely, a lower proportion of patients who had CTC underwent additional colonic investigation because of an inadequate examination or clinical uncertainty than did those who had BE (5·2% *vs* 8·5%; p=0·0005; table 3).

Table 3 Additional colonic investigation in patients who had their randomised procedure, by reason for investigation

		CT colonography (n=1206)	Barium enema (n=2300)	Relative risk (95% CI)	p value
All referrals for additional colonic investigation		283* (23·5%)	422† (18·3%)	1·28 (1·12–1·46)	0·0003
Colorectal cancer or polyp ≥10 mm suspected		133 (11·0%)	173 (7·5%)	1·47 (1·18–1·82)	0·0005
	Colorectal cancer	68 (5·6%)	86 (3·7%)	..	..
	Polyp ≥10 mm	65 (5·4%)	87 (3·8%)	..	..
Smaller polyp suspected		87 (7·2%)	54 (2·3%)	3·07 (2·20–4·28)	<0·0001
	8–9 mm	18 (1·5%)	18 (0·8%)	..	..
	6–7 mm	34 (2·8%)	12 (0·5%)	..	..
	≤5 mm	35 (2·9%)	24 (1·0%)	..	..

Data are number (%) unless otherwise specified.

*** 259 patients were referred to endoscopy, six to radiology, and 18 directly to surgery.**

† 368 patients were referred to endoscopy, 29 to radiology, and 25 directly to surgery.

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In patients having additional investigation after the randomised procedure, a colorectal cancer or large polyp was diagnosed in a similar proportion of patients in the CTC and BE groups, both overall (29% *vs* 28%, respectively) and specifically in patients having an additional procedure to investigate large or · lesions (table 4).

Table 4 Results of additional colonic investigation in patients who had their randomised procedure, by reason for investigation

		CT colonography				Barium en
		Additional colonic procedure undertaken	Colorectal cancer detected	Polyp ≥10 mm detected	Colorectal cancer or polyp ≥10 mm detected	Additional colonic procedure undertake
All referrals for additional colonic investigation		283	40*	43	83* (29%)	422
Colorectal cancer or polyp ≥10 mm suspected		133	39	35	74 (56%)	173
	Colorectal cancer	68	36	2	38	86
	Polyp ≥10 mm	65	3	33	36	87
Smaller polyp suspected		87	1	8	9 (10%)	54
	8–9 mm	18	1	5	6	18

Data are number, or number (%). Only the most advanced lesion per patient is presented.

*** Two further patients had inoperable colorectal cancer found at CT colonography, and a subsequent colonic procedure was not undertaken.**

† 5 mm sigmoid colon polyp at CT colonography, and a 10 mm sessile caecal polyp at subsequent colonoscopy.

‡ Of these four patients, the first had a 5 mm caecal polyp at barium enema, and a 40 mm sessile caecal polyp at subsequent colonoscopy; the second had a 5 mm proximal sigmoid colon polyp at barium enema, and a 15 mm sessile descending colon polyp at subsequent colonoscopy; the third had a 5 mm descending colon polyp at barium enema, and a 10 mm wide-stalked sigmoid colon polyp at subsequent colonoscopy; the fourth had a 5 mm rectal polyp at barium and a 30 mm sigmoid colon cancer at subsequent colonoscopy.

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At least one previously unknown extracolonic finding was reported in 673 (57·8%) of the 1164 patients who had CTC and did not have colorectal cancer diagnosed before discharge. A referral for additional investigation was made in 87 (7·5%) patients, leading to diagnosis of extracolonic malignancy in 13 (see appendix), aortic aneurysm of 5·5 cm diameter or larger (the recommended threshold for surgical referral)[22] in five, and aortic aneurysm of 3·0–5·4 cm (recommended for surveillance)[22] in 20. Of 87 patients referred for additional procedures, 31 (36%) were given an extracolonic diagnosis that explained at least one of their presenting symptoms. A more detailed analysis will be published elsewhere.[16]

We analysed the data in June, 2012, when registration was reported to be 97% complete for cancers diagnosed until December, 2010[23] (at which point all patients had been followed up for at least 36 months), and all deaths until December, 2011, had been registered.[24] At the time of analysis (median follow-up for deaths 5·4 years, IQR 4·7–6·0), 400 (15·8%) patients assigned to BE and 201 (15·7%) assigned to CTC had died (p=0·94).

During the 3 year follow-up, colorectal cancer was subsequently diagnosed in three patients who had undergone CTC and 12 who had undergone BE, giving a miss rate of 7% (three of 45) for patients who had CTC and 14% (12 of 85) for those who had BE (difference −7, 95% CI −18 to 3; p=0·21). BE had a miss rate of 10% (five of 48) for distal cancers (up to and including the sigmoid colon) and 19% (seven of 37) for proximal cancers. The number of missed cancers after CTC was too small to undertake separate analyses of proximal and distal cancers.

During the 3 year follow-up, 78 primary extracolonic cancers were diagnosed in the CTC group and 131 in the BE group (see appendix); incidence did not differ between groups (21·3 per 1000 person-years in the CTC group *vs* 18·0 per 1000 person-years in the BE group; incidence rate ratio [IRR] 1·18, 95% CI 0·89–1·57; p=0·24). In the first year, rates of primary extracolonic cancer diagnosis in the trial cohort were nearly twice as high as expected (IRR 1·88, 1·33–2·65; p=0·0002), but again rates did not differ significantly between the CTC and BE groups (IRR 0·84, 0·54–1·30; p=0·43). CTC detected 11 (39%) of 28 extracolonic cancers diagnosed during the first year, whereas BE detected four (6%) of 66.

Minor adverse effects are reported elsewhere;[14] we report more serious adverse events here. An unplanned hospital admission within 30 days occurred in 25 patients after BE and 14 after CTC. The expert panel judged five admissions as possibly attributable to a randomised procedure. Four occurred after BE (cardiac arrest, one abdominal pain, one rectal bleeding, and one collapse after procedure). Another had free gas seen in the abdomen during CTC and was admitted with a suspected pe on

was treated conservatively. Three patients died within 30 days of BE—at 5 days (cardiac failure), 25 days (liver failure), and 28 days (perforated viscus)—and one after CTC, at 30 days (obstructive pulmonary disease).

Discussion

This is the first randomised trial comparing CTC and BE for diagnosis of colorectal cancer or large polyps in symptomatic patients (see panel). It is also the first trial to compare rates of additional colonic investigation when the two tests are used in normal clinical practice. Our results show that CTC detected significantly more cancers or large polyps than did BE, suggesting that it is more sensitive for detection of such lesions. However, rates of additional colonic investigation were higher after CTC than after BE, due to higher detection rates of both large and small polyps.

- Panel

Research in context

Systematic review

We searched the Medline database for reports on CT colonography (CTC) published between 1994 and 2003, with the terms “colonography”, “colography”, “CT colonoscopy”, “CT pneumocolon”, “virtual colonoscopy”, and “virtual endoscopy”. We did not apply any language restrictions. Additional searches using the Cochrane controlled trials register, Embase, Science Citation Index, and manual searches of key journals did not reveal any additional studies. 24 studies that met selection criteria were included in a meta-analysis, which showed that CTC was highly sensitive for the detection of colorectal cancer. However, we found no randomised trials comparing CTC with barium enema (BE), which remains widely used.

Interpretation

Our study is the first randomised trial to compare CTC and BE for investigation of patients with symptoms suggestive of colorectal cancer. We report that CTC detects significantly ore colorectal cancers or large polyps than does BE, and has a lower miss rate fo lorectal cancer. CTC is a less burdensome procedure than BE, particularly for ol

patients, and studies have shown that patients prefer CTC to BE.[10, 11, 12, 14] Additionally, CTC offers the possibility of referring patients for same-day colonoscopy, which is impossible after BE. Taken together, these findings suggest that CTC should replace BE in this patient group. We also concluded that CTC leads to more follow-up tests than does BE. More widespread implementation of CTC should therefore be accompanied by protocols to optimise the sensitivity and specificity of the procedure, guidelines on reporting and patient referral, adequate training, and a system of continuous audit.

Consistent with its higher sensitivity, CTC missed fewer colorectal cancers than did BE (7% *vs* 14%). This difference was not statistically significant, but the miss rate of BE in this trial is similar to rates reported in several clinical audits.[1, 25, 26, 27] No audit data are available for miss rates after CTC in routine clinical practice, although in the parallel trial of CTC versus colonoscopy,[13] one of 29 cancers was missed by CTC. In a recent meta-analysis of 25 studies (9223 patients) in which CTC was compared with colonoscopy, the relative sensitivity of CTC for colorectal cancer was 96% (95% CI 94–98).[28]

FS might have been undertaken before CTC and BE in some centres because some physicians believe that radiological tests are less sensitive in the distal colon and rectum than is endoscopy. However, our results and those of previous audits show that the miss rate for colorectal cancer after BE is no higher in the left than the right colon.[1, 25]

We report that significantly more large polyps were detected with CTC than with BE (p=0·0098). We could not directly calculate the miss rate for large polyps because colonoscopy was not used as a reference standard and no polyp registry exists. However, in the only study[29] in which all participants had BE, CTC, and colonoscopy, per-patient sensitivity for lesions of 10 mm or larger was only 48% (95% CI 35–61) for BE and 59% (46–71) for CTC. A similarly low sensitivity of 55% (40–70) was reported in a study of 600 patients having CTC before clinically indicated colonoscopy.[30] These figures conflict with the results of two meta-analyses showing sensitivities for large polyps of 85% (95% CI 79–91)[31] and 93% (73–98)[5] for CTC. Studies using multidetector scanners, lower collimations, and a higher-than-average proportion of 3D reading tend to report higher sensitivities than studies that do not use these measures;[31] individual variability in the skills of radiologists is also likely to play an important role.[32, 33, 34] In our trial, recommended methods for CTC were based on the contemporary consensus on best practice,[18] which still meets minimum standards.[35, 36] The radiologists had all interpreted CTC before, and those who had interpreted fewer than 100 cases were given additional training. Continued development of clinical guidelines and a system of sed training and testing will be needed as CTC becomes more widely used, along wit sec

retraining when needed, which has been shown to substantially improve radiologists' ability to identify lesions.[37]

In our trial, patients were referred for additional colonic investigation more frequently after CTC than after BE because of higher detection rates of both large and small polyps in the CTC group. Patients with radiologically detected polyps smaller than 10 mm need to be carefully managed, since most small lesions have low malignant potential and are unlikely to cause symptoms. However, larger lesions (including one cancer) were confirmed in a third of patients referred after detection of polyps measuring 8–9 mm at CTC, indicating a possible benefit of lowering the referral threshold to 8 mm. We found a low yield of cancers and large polyps in patients referred after detection of smaller polyps at CTC. However, after detection of polyps that were 5 mm or smaller at BE, four large lesions (including one cancer) were identified, suggesting that it might be difficult to measure the size of sessile lesions at BE.

A potential advantage of CTC is that patients can have colonoscopy on the same day to remove a lesion or take a biopsy sample. Colonoscopy cannot be undertaken on the same day as BE because of residual barium suspension; patients need to attend the clinic again and undergo a second bowel preparation. However, same-day colonoscopy is only possible if CTC findings are reviewed promptly and if endoscopy departments have adequate capacity. In this trial, only five patients had a follow-up endoscopy on the same day as CTC.

Evidence suggests that patients prefer CTC to BE.[10, 11, 12] In this trial, patients who had BE reported lower satisfaction and greater physical discomfort during and after the procedure than patients who had CTC.[14] BE is also more physically demanding because several patient positions are needed, whereas only two (usually prone and supine) are needed for CTC. This feature of CTC makes it more suitable than BE for frail elderly patients, who account for many of those with symptoms.

Patients regard detection of extracolonic lesions as an advantage of CTC.[38] In this trial, 7·5% of patients who had CTC underwent further investigation as a result of an extracolonic finding. In some cases the finding was unlikely to have caused symptoms, but was nevertheless clinically important (eg, aortic aneurysm). Most patients, however, were diagnosed with minor abnormalities, unlikely to result in any serious health problems if left undetected.[16] We also note that CTC did not detect all extracolonic cancers that were likely to have caused symptoms, and time to diagnosis was not shorter than for patients randomly assigned to BE (appendix). This finding might be due to patients having subsequent tests to investigate persistent symptoms, but needs further investigation.

The health economic analysis of the trial is reported in more detail elsewhere.[16] The mean incremental · each additional colorectal cancer or large polyp detected by CTC was £4235 at 2010- ces

reflecting both the higher unit cost of CTC compared with BE and the cost of investigation and treatment of the detected colonic lesions. CTC is therefore more expensive than BE, but the additional cost might be justified if a mortality benefit can be shown. We extrapolated the number of life-years saved over 20 years by taking into account patient age, stage of cancer, and transition probabilities from the scientific literature. CTC yielded 21 additional life-years per 1000 patients, with an incremental cost per life-year gained of £2684 for CTC compared with BE. With discounting (3·5% per year as recommended by the National Institute for Health and Clinical Excellence [NICE]), the incremental cost per life-year saved was £3486, making it probable that CTC would fulfil the NICE criteria for cost-effectiveness.

Results of our study show that CTC is more sensitive than BE for detection of colorectal cancer or large polyps, and we have reported previously that CTC is preferred by patients.[14] The higher sensitivity of CTC for small polyps and its ability to detect extracolonic lesions offer equivocal benefits, since these incur additional costs and patients might be referred for investigation of findings that are clinically unimportant. However, this risk can be managed if more widespread use of CTC is accompanied by protocols for best practice, including guidelines on patient referral for both radiologists and referring clinicians. Training and quality assurance for radiologists are also needed if the capabilities of CTC are to be fully realised. With these provisos, our results suggest that CTC should now replace BE as the preferred radiological test for patients with symptoms suggestive of colorectal cancer.

Contributors

SH and WA were joint principal investigators. They designed the study and wrote the grant application, assisted by CvW, RE, CK, RJL, DM, and JW. RE generated the randomisation codes and designed the study database. ED, IK-H, and WA were responsible for recruitment, data collection, and management, assisted by the SIGGAR investigators mentioned below. KW, ED, IK-H, and WA analysed the data, and CvW, GY, RJL, and JW analysed subsets of the data. SH, ED, and WA drafted the report and all authors contributed to review and revision. All authors have seen and approved the final version. Both SH and WA will act as guarantors.

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Conflicts of interest

SH and DB have been remunerated for research and development advice by Medicsight, a software company developing computer-assisted detection for CT colonography. The other authors declare that they have no conflicts of interest.

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Supplementary Material

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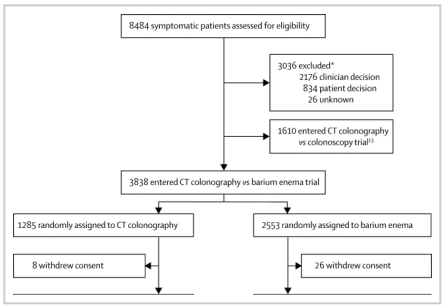

Figure 1 Trial profile

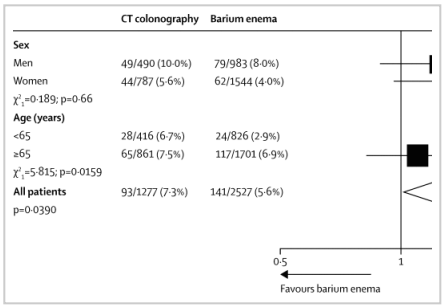

Figure 2 Detection of colorectal …

Tables

Table 1: Characteristics of patients included in this trial versus excluded patients

Table 2: Detection rates of colorectal cancer and large polyps

Table 3: Additional colonic investigation in patients who had their randomised procedure, by reason for investigation

Table 4: Results of additional colonic investigation in patients who had their randomised procedure, by reason for investigation

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