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# Patient experience of colon capsule endoscopy in clinical practice: a structured, comparative patient survey

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## ABSTRACT

**Objective** Colon capsule endoscopy (CCE) is a recognised diagnostic tool, but there is little research exploring patient experience of this relatively new technology. We aimed to understand the patient experience of CCE and explore similarities to and differences from colonoscopy and CT colonography (CTC).

**Methods** We conducted a structured patient experience survey exploring preprocedural, procedural and postprocedural elements of CCE, alongside colonoscopy and CTC, using descriptive statistics. Consenting patients were recruited from the NHS England CCE pilot, referred either on a suspected colorectal cancer or a 3-year postpolypectomy surveillance pathway.

**Results** 927 of 1937 patients (48%) responded to the survey invitation. 486 had CCE as their index procedure, 399 colonoscopy and 42 CTC. Two per cent of CCE patients found the procedure painful compared with 21% of colonoscopy and 12% of CTC patients (p<0.001). The CCE procedural information was easily understood by 81% of patients compared with 92% having colonoscopy (p<0.001). There was no significant difference in the bowel preparation experience with 20% of CCE and 16% of colonoscopy patients experiencing severe or more discomfort (p=0.439). However, 19% of CCE patients felt the bowel preparation would put them off a future CCE compared with 8% of colonoscopy patients (p<0.001). This was not wholly explained by the need for further investigations. Using regression analysis, we found that high-quality preprocedural information, tolerability of bowel preparation, procedural comfort and investigative closure were predictors of patient satisfaction with CCE. 74% of patients were satisfied with CCE in diagnosing or reassuring them compared with 91% in colonoscopy and 80% in CTC (p<0.001).

**Conclusions** CCE was similarly or better tolerated than colonoscopy and CTC throughout the patient journey, with significantly less pain experienced. A future CCE clinical service should ensure that the patient is well informed and optimise the likelihood of the investigative closure.

### WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Colon capsule endoscopy (CCE) is a relatively novel colorectal diagnostic that requires the active participation of the patient to ensure an optimal diagnostic result. There is little available structured intelligence of the patient experience to inform the establishment of a future CCE clinical service.

### WHAT THIS STUDY ADDS

⇒ Intuitively CCE is a more attractive diagnostic for patients than colonoscopy. While largely painless, CCE is not without its challenges and may not necessarily be the right test for a patient. Better information is required to support the patient through the procedure, address the difficulty of bowel preparation and the consequences of an inconclusive procedure.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Careful patient selection, high-quality information and a procedural support structure are key to ensuring an optimal role for CCE in a future colorectal diagnostics service.

## INTRODUCTION

In June 2020, NHS England published clinical guidance supporting the use of colon capsule endoscopy (CCE) during the COVID-19 pandemic.[1 2] Its purpose was to help provide additional colorectal diagnostic capacity to sustain and restore endoscopy services. The guidance authorised the use of CCE in pilot sites, in place of colonoscopy, on patients referred with suspected colorectal cancer (CRC), but judged to be at low or intermediate risk or those awaiting postpolypectomy surveillance colonoscopy.[3 4] While CCE is a licensed diagnostic procedure, there had been little experience of its use in England. A CCE service was being evaluated in Scotland (known as the SCOTCAP study), but at the point of the English roll-out, there was little intelligence about how a high-quality, patient-facing CCE service should look.[5 6] The NHS E National Cancer Team allocated funding to conduct a primary study of the safety and diagnostic accuracy and the third element of healthcare quality, 'the patient experience'.[7–9] A central element of the development of any new diagnostic technology is an understanding of the way it is

perceived by the patient. This is particularly the case for CCE because the successful delivery of that diagnostic requires significant patient engagement. In establishing a clinical service for CCE, insights from patient perspectives are essential to refine CCE-based services, improve outcomes and determine whether CCE could be viewed as an acceptable alternative to colonoscopy.

We undertook this pragmatic research study to (a) understand the existing patient experiences of the piloted CCE service in order to better explain the risks and benefits of introducing CCE into a future diagnostic colorectal service and (b) identify possible strategies to optimise those benefits and mitigate the risks of that service.[10] The study compared the experience of CCE patients to that of those undergoing the 'gold standard' diagnostic for CRC, colonoscopy, as their index test (the reference standard). The CCE was also compared with those who underwent CT colonography (CTC) (the other available diagnostic). This was because, like CTC, CCE performs a 'filter function' role, excluding or identifying those with colorectal pathology, prior to a subsequent therapeutic colonoscopy. A parallel qualitative study of the patient experience was also undertaken (results not yet reported).

## METHODS

### Procedures

During 2021 and 2022, patients from 50 secondary care CCE pilot study sites who had undergone either CCE, colonoscopy or CTC as part of the evaluation of the NHS E CCE pilot were additionally asked to consent to explore their experiences of colorectal investigation.[11] The index inclusion criteria had been those patients aged 18 years and over, (1) with a faecal immunochemical test for haemoglobin (FIT) ≤100 µg Hb/g faeces and who were referred for the investigation of suspected CRC or (2) awaiting 3 yearly postpolypectomy surveillance. There had been no formal exclusion criteria for CCE. Instead, CCE selection guidance was provided to clinicians by an Expert Advisory Group (EAG). This stated that patients with dysphagia, stricturing Crohn's disease, long-term daily use of non-steroidal anti-inflammatory drugs, prior abdominopelvic irradiation and during pregnancy may be more suitable for an alternative investigation. Preassessment using radiological imaging or a patency capsule was suggested for those at risk of capsule retention. The EAG also advised that patients with significant comorbidity, the use of opioid or tricyclic antidepressant medication and impaired mobility may predict for poor bowel preparation. However, the choice of test, CCE, colonoscopy or CTC (the latter in symptomatic patients only) was entirely at the discretion and judgement of the responsible clinician and patient.

CCE was performed using the PillCamTM COLON 2 system (Medtronic.com) and was supported by patient facing product literature (medtronic.com/uk-en/pillcamcolon). All pilot sites followed the guidelines of the European Society of Gastroenterological Endoscopy (ESGE) for bowel preparation for CCE.[12–14] This included a 3-day low residue diet followed by two split doses of a polyethylene glycol-electrolyte solution (the evening before and the morning of the procedure), two directed 'boosters' comprising gastrografin and phosphosoda after swallowing the capsule and, if needed, a bisacodyl suppository at the end of the day. Moviprep (Norgine Ltd), or Plenvu (Norgine Ltd) when stocks were depleted, was used. Some centres were not able to access gastrografin and used phosphosoda boosters alone. Following publication of a nested cohort within the CareForColon2015 trial suggesting that prucalopride might improve CCE completion rate and with the support of the EAG, 35 centres added this to their protocol during the evaluation.[15]

In line with ESGE guidelines, the EAG recommended that symptomatic patients with a normal CCE could be discharged and those with ≤3 polyps of <6 mm could be discharged or have a repeat procedure in 3 years.[14] A complete CCE was defined as one where the CCE was seen to be expelled or where the anal cushions were identified and an adequate bowel preparation was defined as a score of ≥6 on the Colon Capsule Clear Score.[16] All CCE video reporters completed an approved online CCE reader training course (Imige Ltd). The CCE quality and safety findings from the NHS E pilot evaluation have recently been reported, confirming that it is safely tolerated in 98.4% of patients and that the per patient sensitivities for ≥10 mm and 6–9 mm polyps are 97% in those with a paired, complete and adequately prepared CCE and colonoscopy.[11]

Colonoscopy and CTC were performed and reported according to the practice of each individual centre with the Boston bowel preparation scale being applied.[17–20]

The sample size for this study was pragmatically determined based on the patients recruited to the pilot evaluation and time and resources available. We estimated it would be possible to recruit a sample of around 1000, sufficient to conduct the planned analyses. A post hoc, power analysis showed that with the final sample of 927, a multiple regression model incorporating 5–10 predictors would provide over 80% power to detect small to medium effect size.[21]

Our reporting follows guidance from the Consensus-Based Checklist for Reporting of Survey Studies (checklist in online supplemental file).[22]

### Questionnaire

No validated CCE patient experience instrument exists. To develop a questionnaire, we first referred to the British Society of Gastroenterology (BSG) position statement on patient experience of GI endoscopy to formulate a framework and then incorporated relevant questions from the validated Gastrointestinal Endoscopy Satisfaction Questionnaire (GESQ).[23 24] These enabled us to construct two of the GESQ subscales: information provided and pain and discomfort. We created additional questions to

enable the exploration of CCE, colonoscopy and CTC in parallel as well as capturing and comparing elements of the patient experience common to all. We structured the questionnaire into time frames: before, during and after the procedure, with additional data collection on demographics, generic health-related quality of life (EQ-5D-5L) and patients' experience of previous colorectal investigations.[25] The preprocedure section of the questionnaire included clinic consultations, the investigation booking process, preassessment, the patient's review of written patient information and consent documentation, bowel cleansing preparation and access to the hospital/unit.

The procedure section explores the patients' physical and psychological experience on the day of the index test, up to and including the procedure itself. When CCE was initiated in a hospital or endoscopy unit, it included the experience from the time of arrival in the department and time in the procedure room. This included interaction with staff, setting up the recording box and swallowing the CCE. CCE has the potential to be delivered safely within a community setting and this was undertaken by a number of Trusts during the evaluation. Questions additionally explored patients' experiences of following instructions for and taking prokinetic medication, the booster preparations, suppository and passage of the capsule.

The postprocedure section included questions about immediate postprocedure recovery and its impact, receiving results and clinical follow-up, including any further diagnostic investigations and the initiation of management plans for any diagnoses. For those undergoing CCE, we also explored patients' understanding of instructions for disconnecting and returning the recorders.

The team initially developing the questionnaire included a gastroenterologist, a health economist with an interest in endoscopy, a medical sociologist and experts in qualitative and quantitative health sciences research. There was then patient and public involvement from the Trust's lay patient panel and from the two patient representatives of the EAG, whose lived experience aligned with the research focus. The EAG provided research oversight during the delivery of the study and were supported by the patient experience team within NHS England and the Public and Patient Voices Forum. The developed questionnaire was distributed to patients who initially had been recruited into the evaluation of the NHS E pilot and consented to be further contacted and then recruited into the patient experience study, after they had undergone CCE, colonoscopy or CTC as part of the primary study (online supplemental appendix A). The median time was 26 weeks after their test (range 2 to 92 weeks), this large window for recruitment reflecting the timeframe required to establish the survey during the COVID-19 pandemic, once the NHS E pilot had begun. Patients, therefore, were reporting their retrospective reflections. They could choose an online (using Qualtrics) or a paper version or have a member of the research team help them complete the questionnaire over the telephone. Questionnaire responses were anonymised and stored in Qualtrics. The data were password-protected and access to the data was restricted to researchers conducting the analysis. Funding was only provided to create an English language version of the questionnaire.

### Analysis

The team preagreed an analysis plan (see online supplemental appendix B). We used descriptive statistics to summarise the questionnaire responses, and $\chi^2$ test, test of proportions, t-test and Analysis of Variance to test for differences between the three groups. Test of proportions and t-tests were used for the subgroup analyses. A logistic regression model explored the relationship between satisfaction and experiences during and before the procedures, including variables for the GESQ score, previous treatment, age and sex. Due to low numbers in the CTC group, we conducted these comparative analyses for the CCE and colonoscopy groups only. All analyses were conducted in SPSS V.29.

## RESULTS

We distributed 1937 questionnaires to all available eligible potential participants during the recruitment window (CCE=1108; colonoscopy=746; and CTC=83) and received 927 survey responses, giving a response rate of 48%. This included returns from those with experience of CCE (n=486), colonoscopy (n=399) and CTC (n=42). All patients had been referred with suspected CRC bar 14 CCE and 1 colonoscopy participant, whose indication was postpolypectomy surveillance. The CCE responses were obtained from 26 sites, ranging from 2 to 76 participants per site. Fifty-four per cent of the CCE cohort were female and the mean age was 67 years for males, and 63 years for females (table 1). This is similar to that of the whole population evaluated in the primary CCE study (55% female and a mean age of 60 years for both males and females).[11] CCE patients were significantly younger than colonoscopy and CTC patients (p<0.001). The study population was predominantly white with 99% of patients across the three groups identifying as such. Approximately half of those attending for CCE and colonoscopy had undergone a previous investigation, compared with three quarters of patients having CTC. CCE transit time was not reported in this patient experience survey.

### Preprocedural findings

Patients were largely satisfied with the information received prior to the procedure, as measured using the GESQ score, with similar findings for patients who had CCE and colonoscopy. While the preprocedural information was easy to understand for 81% of CCE patients (with 84% also finding it useful), a higher proportion of colonoscopy patients found the information easy to understand (92%) and useful (94%) (p<0.001).

**Table 1** Comparison between CCE, colonoscopy and CTC: summary of all three questionnaires

| | | CCE N=486 | Colonoscopy N=399 | CTC N=42 | P value |
|---|---|---|---|---|---|
| Sex | % Female | 259/484 (54%) | 200/398 (50%) | 21/42 (50%) | 0.607 |
| Ethnicity | % White | 478/483 (99%) | 393/396 (99%) | 42 (100%) | 0.446 |
| Age: mean (SD) | Male | 66.6 (10.3) | 71.6 (10.4) | 76.5 (7.0) | <0.001 |
| | Female | 63.1 (11.8) | 67.0 (13.2) | 74.7 (9.4) | <0.001 |
| Previous investigation | % Yes | 226/477 (47%) | 205/394 (52%) | 33/42 (76%) | <0.001 |
| Preprocedural experience | | | | | |
| Preference for another procedure | % Yes | 86/469 (18%) | 131/382 (34%) | 8/40 (20%) | <0.001 |
| Concern for | Safety | 71/484 (15%) | 50/393 (13%) | 4/42 (10%) | 0.516 |
| | Efficacy | 121/484 (25%) | 43/394 (11%) | 5/41 (12%) | <0.001 |
| Information before procedure | Easy to understand | 393/486 (81%) | 363/396 (92%) | 32/42 (76%) | <0.001 |
| | Useful | 406/485 (84%) | 374/398 (94%) | 31/42 (74%) | <0.001 |
| Did you feel involved in decision to have procedure? | Yes | 380/483 (78%) | 330/396 (83%) | 26/41 (63%) | 0.006 |
| Bowel preparation (% severe/very severe) | Discomfort | 95/482 (20%) | 65/397 (16%) | 8/42 (19%) | 0.439 |
| | Pain | 33/484 (7%) | 30/396 (8%) | 3/42 (7%) | 0.910 |
| | Anxiety | 72/482 (15%) | 42/397 (11%) | 7/42 (17%) | 0.128 |
| Put off future bowel procedure due to bowel prep | % Yes | 94/484 (19%) | 33/397 (8%) | 6/42 (14%) | <0.001 |
| Experience of the procedure | | | | | |
| Procedure (% severe/very severe) | Discomfort | 20/482 (4%) | 80/397 (20%) | 7/42 (17%) | <0.001 |
| | Pain | 8/482 (2%) | 85/398 (21%) | 5/42 (12%) | <0.001 |
| | Anxiety | 46/484 (10%) | 58/398 (15%) | 7/42 (17%) | <0.001 |
| Postprocedural experience | | | | | |
| Postprocedure (% severe/very severe) | Discomfort | 15/485 (3.1%) | 19/399 (4.8%) | 1/42 (2.4%) | 0.384 |
| | Pain | 9/481 (1.9%) | 16/397 (4.0%) | 1/42 (2.4%) | 0.155 |
| | Anxiety | 21/484 (4.3%) | 16/398 (4.0%) | 5/42 (11.9%) | 0.063 |
| Results—explanation of findings easy to understand | % Yes | 343/478 (72%) | 303/391 (77%) | 28/42 (67%) | 0.086 |
| Results—explanation of findings useful | % Yes | 313/478 (66%) | 295/282 (77%) | 21/42 (50%) | <0.001 |
| Further bowel investigations | % Yes | 248/482 (52%) | 64/391 (16%) | 13/38 (34%) | <0.001 |
| Overall experience | | | | | |
| GESQ subscales (0 to 100, 100=better) | Pain | 90.2 (15%) | 72.1 (21%) | 71.4 (21%) | <0.001 |
| | Information | 80.9 (16%) | 81.9 (14%) | 73.2 (17%) | 0.003 |
| Satisfied in diagnosing or reassuring you? | % Satisfied/very satisfied | 357/483 (74%) | 353/390 (91%) | 33/41 (80%) | <0.001 |
| Satisfied to have same procedure in future? | % Satisfied/very satisfied | 309/484 (64%) | 264/390 (68%) | 32/42 (76%) | 0.173 |
| Procedure right test for you? | % Yes | 315/482 (65%) | 323/394 (82%) | 32/40 (80%) | <0.001 |

CCE, colon capsule endoscopy; CTC, CT colonography; GESQ, Gastrointestinal Endoscopy Satisfaction Questionnaire.

Patients expressing concerns about the safety of each of the procedures did not differ significantly (15% of CCE patients, 13% colonoscopy and 10% CTC expressed concerns) (p=0.516). More patients expressed concerns about the effectiveness of CCE (25%) compared with colonoscopy (11%) and CTC (12%) (p<0.001). 79% of the patients felt involved in the decision to have a CCE; this was similar to colonoscopy (83%) but was significantly higher than for CTC (63%) (p<0.001).

Looking back to their thinking before the intervention, 18% of CCE patients said that they would have preferred a different procedure; this was lower than colonoscopy (34%), but not different from CTC patients (20%) (p<0.001). For those 207 CCE patients who had a previous colonoscopy, 31 (15%) would have preferred colonoscopy to CCE.

Tolerability of the bowel preparation for CCE patients, in terms of discomfort, pain or anxiety experienced, was not statistically different from colonoscopy. However, when asked whether the bowel preparation would put them off another procedure in the future, a much higher proportion of CCE patients reported they would be put off (19%) compared with colonoscopy (8%) (p<0.001; table 1).

## Procedural findings

Although 39% of patients thought the capsule was larger than expected, only 4% found it difficult to swallow. Almost everyone who received instructions from the recording device to take boosters was able to take them, although 19% found it difficult or very difficult to do so. A suppository was used by 41% to pass the capsule—16% struggled with this, and 82% saw that the capsule had passed through the body. Only 6% of patients stated that they found the recording equipment difficult to use (the causes of which are not reported) and nearly all patients (99%) reported no difficulty in returning the equipment (table 2).

The CCE procedure itself was significantly less painful for patients than colonoscopy and CTC (p<0.001). CCE patients also reported significantly less discomfort and were less anxious during the procedure (table 1).

Over a quarter of patients having CCE contacted their clinical support team during the investigative episode. Nearly all CCE patients (98%) had been given a contact number in case of any problems and 28% used it. This compares to colonoscopy patients where 98% had been giving a contact number and only 3% used it (online supplemental appendix C1 and C2).

## Postprocedural findings

Following the procedures, measures of pain and discomfort were low and similar in all groups although those having CCE reported less pain (table 1) (p=0.155). Overall, colonoscopy patients reported more favourably than CCE patients on the results process, 22% of CCE patients felt they did not receive enough explanation about the findings compared with 11% for colonoscopy (online supplemental appendix C1 and C2). However, CCE patients tended to be more satisfied than CTC patients, 26% of whom reported not receiving enough explanation (online supplemental appendix C3).

Over half of CCE patients (52%), a much higher proportion than colonoscopy (16%) or CTC (34%) had a further bowel investigation after the procedure. Reasons given for this were that the CCE was not sufficiently conclusive (26%), the CCE found a problem, which required a colonoscopy to treat (21%) and that the CCE was normal, but symptoms continued (3%) (online supplemental appendix C1 C1). Perhaps related to this, looking back on the experience, 65% of CCE patients felt that CCE was the right test for them, compared with 82% for colonoscopy and 80% for CTC (p<0.001; table 1).

## Subgroup analysis

We explored sex and age differences in experience through subgroup analysis, excluding the CTC group because of the small sample. For both colonoscopy and CCE, significantly more women than men reported severe pain, discomfort and anxiety during the bowel preparation process (table 3). For both CCE and colonoscopy, women were significantly less likely to be satisfied and to feel that the procedure was the right test for them, compared with men. In the CCE group, however, women were significantly more likely to be 'put off' having a future procedure because of the bowel preparation process (30% of women vs 8% of men). This does not appear to be wholly due to the need for further investigation after CCE, which was the same for women (53%) and men (50%; p=0.611).

During the CCE procedure, women reported significantly more discomfort (7% vs 1% of men) and anxiety (15% vs 4% of men); these differences were largely replicated in the colonoscopy group. There were no significant differences found between age groups (<70 and 70+ years) for the same comparisons. Full subgroup analysis results are found in online supplemental appendix D.

## Predicting satisfaction

We explored three measures of patient satisfaction, based on the following questions:

1. Overall, how satisfied are you with your CCE in diagnosing or reassuring you?
2. If, in the future, you have to have another bowel investigation, how satisfied would you be to have another CCE?
3. Looking back on your whole experience, do you feel that CCE was the right test for you?

74% of respondents were satisfied with CCE in terms of diagnosis or reassurance, compared with 91% in colonoscopy and 80% CTC (p<0.001). 64% of CCE patients were satisfied to have the same procedure in future compared with 68% for colonoscopy and 76% for CTC (p=0.173). Looking back on the whole experience, 65% were satisfied that CCE was the correct test for them, fewer than colonoscopy (82%) or CTC (80%) (p<0.001).

Table 2 Exploring aspects of CCE

| | | N |
|---|---|---|
| Preference prior to procedure (for patients previously had a colonoscopy) | Prefer colonoscopy to CCE | 31/207 (15%) |
| Were you able to choose between setting up the recording equipment and swallowing the Colon Capsule in hospital or at home? | Yes | 61/481 (13%) |
| Where did you swallow the colon capsule? | At home | 12/484 (2%) |
| | In hospital | 472/484 (98%) |
| What did you think of the size of the capsule? | Smaller than, ie, expected | 76/481 (16%) |
| | About the size, ie, expected | 220/481 (46%) |
| | Larger than, ie, expected | 185/481 (39%) |
| How easy did you find swallowing the capsule? | Very easy/easy<br>Difficult/very difficult | 399/484 (82%)<br>18/484 (4%) |
| How easy did you find using the recording equipment? | Very easy/easy<br>Difficult/very difficult | 344/484 (71%)<br>30/484 (6%) |
| Were there any difficulties returning the equipment? | No | 472/482 (98%) |
| During the CCE, did you receive an alert to take the first booster? | Yes | 435/481 (90%) |
| Did you take the first booster? | Yes | 421/481 (88%) |
| During the CCE, did you receive an alert to take a second booster? | Yes | 326/416 (78%) |
| Did you take the second booster? | Yes | 316/416 (76%) |
| How easy did you find it to use the booster(s) during your CCE? | Very easy/easy<br>Difficult/very difficult | 251/416 (60%)<br>77/484 (16%) |
| During your CCE did you need to use the suppository? | Yes | 196/482 (41%) |
| Did you see the capsule come out? | Yes | 398/483 (82%) |
| Were there any unexpected complications with your procedure? | I could not swallow the capsule | 0 |
| | I struggled to swallow the capsule | 14/482 (3%) |
| | The capsule made me choke | 1/482 (<1%) |
| | The capsule got stuck in my bowels | 28/482 (6%) |
| | The capsule was retained | 12/482 (3%) |
| | I had problems with the recording equipment | 43/482 (9%) |
| | Other<br>Battery failure<br>Did not record<br>Problem passing capsule<br>Other reason | 16/482 (3%)<br>19/482 (4%)<br>16/482 (3%)<br>41/482 (9%) |
| | None | 327/482 (68%) |

CCE, colon capsule endoscopy.

Focusing on patients' response to whether they thought the procedure was the right test for them (yes/no) as a measure of satisfaction in a logistic regression, we modelled CCE and colonoscopy separately. For CCE patients, the logistic regression model showed that significant predictors of being satisfied that CCE was the right test were receiving better information prior to the procedure (higher GESQ information score, OR 1.04 95% CI (1.03 to 1.06)) and experiencing less pain during and after the procedure (higher GESQ pain score, OR 1.03 95% CI (1.01 to 1.05)), which both increased the likelihood of being satisfied. Requiring a further bowel procedure (OR 0.26, 95% CI (0.16 to 0.43)) and being put off a future procedure by the bowel preparation (OR 0.18, 95% CI (0.10 to 0.34)) decreased the likelihood of being satisfied (table 4). Age, gender and any previous investigations were not significant predictors of satisfaction. For those who did not have any further investigations, 87% were satisfied CCE was the right test for them. By contrast, those who went on to have

Table 3 Subgroup analysis: male and female

| | | CCE N=486 | | | Colonoscopy N=399 | | |
|---|---|---|---|---|---|---|---|
| | | Male N=225 (46%) | Female N=259 (54%) | P value | Male N=198 (50%) | Female N=200 (50%) | P value |
| Age mean (SD) | Male | 66.6 (10.3) | 63.1 (11.8) | <0.001 | 71.6 (10) | 67.0 (13) | <0.001 |
| Previous investigation | % Yes | 98/220 (45%) | 127/255 (50%) | 0.211 | 101/195 (52%) | 103/198 (52%) | 0.916 |
| GESQ mean (SD) (0–100, 100=better) | Pain | 93.8 (11) | 86.9 (18) | <0.001 | 77.6 (19) | 66.6 (22) | <0.001 |
| | Information | 84.2 (15) | 78.1 (17) | <0.001 | 82.1 (15) | 81.6 (13) | 0.355 |
| Bowel preparation (% severe/very severe) | Discomfort | 20/224 (9%) | 75/256 (29%) | <0.001 | 18/197 (9%) | 47/199 (24%) | <0.001 |
| | Pain | 4/225 (2%) | 29/257 (11%) | <0.001 | 4/197 (2%) | 26/198 (13%) | <0.001 |
| | Anxiety | 10/225 (4%) | 62/255 (24%) | <0.001 | 12/198 (6%) | 30/198 (15%) | 0.003 |
| Put off future procedure due to bowel prep? | % Yes | 17/225 (8%) | 77/257 (30%) | <0.001 | 12/197 (6%) | 21/199 (11%) | 0.108 |
| Procedure (% severe/very severe) | Discomfort | 3/224 (1%) | 17/256 (7%) | 0.004 | 22/198 (11%) | 58/198 (29%) | <0.001 |
| | Pain | 1/223 (<1%) | 7/257 (3%) | 0.052 | 21/198 (11%) | 64/199 (32%) | <0.001 |
| | Anxiety | 8/225 (4%) | 38/257 (15%) | <0.001 | 15/198 (8%) | 43/199 (22%) | <0.001 |
| Postprocedure (% severe/very severe) | Discomfort | 2/225 (1%) | 13/258 (5%) | 0.009 | 6/198 (3%) | 13/200 (7%) | 0.105 |
| | Pain | 2/223 (1%) | 7/256 (3%) | 0.140 | 4/198 (2%) | 12/198 (6%) | 0.041 |
| | Anxiety | 0/225 (0%) | 21/258 (8%) | <0.001 | 2/198 (1%) | 14/199 (7%) | 0.002 |
| Further bowel investigations? | % Yes | 113/225 (50%) | 134/255 (53%) | 0.611 | 28/194 (14%) | 35/196 (18%) | 0.358 |
| Satisfied in diagnosing or reassuring you? | % Satisfied/ very satisfied | 178/224 (80%) | 177/257 (69%) | 0.008 | 177/192 (92%) | 175/197 (89%) | 0.259 |
| Satisfied to have same procedure in future? | % Satisfied/ very satisfied | 169/225 (75%) | 138/257 (54%) | <0.001 | 147/192 (77%) | 116/197 (59%) | <0.001 |
| Procedure right test for you? | % Yes | 170/224 (76%) | 143/256 (56%) | <0.001 | 167/194 (86%) | 155/199 (78%) | 0.035 |

CCE, colon capsule endoscopy; GESQ, Gastrointestinal Endoscopy Satisfaction Questionnaire.

further investigations, 62% were satisfied CCE was right for them.

Similar to CCE, significant predictors of satisfaction with colonoscopy were better information before the procedure, less pain and not being put off by the bowel preparation. Being older was a significant predictor in being satisfied with colonoscopy and, unlike CCE, having to undergo further investigation did not influence satisfaction (although numbers needing further investigation were much smaller in this group) (table 4).

Analysis of the additional satisfaction measures (satisfaction with diagnosis and reassurance and willingness to have the procedure again if necessary) found similar significant predictors to those for the right test. This was true for both CCE and colonoscopy (see online supplemental appendix D).

## DISCUSSION

With a novel diagnostic intervention such as CCE, the safety and clinical effectiveness of the procedure depend on patient engagement.[26] This patient experience survey, and a parallel qualitative study (results not yet reported), complements the multicentre study of CCE safety and diagnostic accuracy in clinical practice, conducted as an NHS E pilot during the COVID-19 pandemic.[11] Its purpose is to better understand how patients experienced all aspects of CCE (in comparison with colonoscopy and CTC) and so inform the possible role of CCE in any future colorectal diagnostics service. Since no validated CCE patient experience instrument exists, we sought to develop a pragmatic questionnaire that would capture the totality of the patient experience and would highlight any areas of concern. We referred to the existing BSG position statement on the patient experience in lower gastrointestinal endoscopy and incorporated the validated GESQ to develop that framework. We additionally included the EQ-5D-5L and recorded patient's prior

Table 4 Logistic regression predicting satisfaction that procedure was the right test

| | CCE | | Colonoscopy | |
|---|---|---|---|---|
| | OR 95% (CI) | P value | OR 95% (CI) | P value |
| Age (years) | 0.985 (0.963 to 1.007) | 0.180 | 1.028 (1.001 to 1.056) | 0.040 |
| Female | 0.659 (0.397 to 1.096) | 0.108 | 1.036 (0.545 to 0.1.971) | 0.914 |
| GESQ information before procedure (0 to 100, 100=better) | 1.042 (1.026 to 1.058) | <0.001 | 1.026 (1.005 to 1.048) | 0.017 |
| GESQ pain (0–100, 100=better) | 1.030 (1.013 to 1.047) | <0.001 | 1.039 (1.023 to 1.055) | <0.001 |
| Would bowel prep put you off another procedure in future? (yes) | 0.183 (0.099 to 0.337) | <0.001 | 0.173 (0.071 to 0.422) | <0.001 |
| Any previous investigations? (yes) | 0.778 (0.478 to 1.268) | 0.314 | 0.569 (0.288 to 1.124) | 0.105 |
| Further investigations? (yes) | 0.260 (0.219 to .575) | <0.001 | 1.427 (0.622 to 3.270) | 0.401 |
| Constant | 0.064 | 0.023 | 0.011 | <0.001 |

CCE, colon capsule endoscopy; GESQ, Gastrointestinal Endoscopy Satisfaction Questionnaire.

experiences. From this, an extensive and detailed survey was created that, we believe, provides an informative baseline from which an optimal patient-facing service could be developed. CCE requires the active participation of the patient to ensure an optimal outcome, arguably beyond that of colonoscopy and CTC.[5 27–32] Appropriate patient selection is integral to its filter function role in a capacity constrained colorectal diagnostics service.[33 34] Our aims in the questionnaire were, therefore, to better understand those elements of the CCE diagnostic process that would help the patient feel that it was the right test for them. Beyond procedural comfort, this included the patient experience of bowel preparation (including the importance of good bowel preparation, the information and guidance given beforehand and the format and clarity of instructions provided), the complexities of the procedure itself and the aftercare options.[35–39] For some, CCE will have meant the closure of the clinical episode and for others further investigation or therapy.[40] The experience of previous investigations on the patient's perception of CCE also needed to be understood.[41]

82% of patients found the CCE easy or very easy to swallow, 4% finding it difficult with one patient reporting choking without inhalation. Safety concerns were not borne out by reported complication rate.[11] The procedural instructions were generally followed without difficulty. Patients experienced less discomfort, pain and anxiety during CCE compared with colonoscopy and CTC. This applied both to men and women. Women particularly struggled with colonoscopy. Bowel preparation for colonoscopy was uncomfortable for a quarter and a third experienced severe or very severe procedural pain and were reluctant to have a future colonoscopy (table 3). These findings reinforce the existing literature describing the challenges faced by many colonoscopy patients in England and are higher than often reported by national audits.[42–44] Despite improvements in recent years, colonoscopy can be a painful and challenging procedure for some, sufficient to deter engagement, despite symptoms that may herald a disease as time sensitive and life changing as CRC.[8 9]

Women found CCE to cause more discomfort, pain or anxiety during the procedure than men. This may point to the complexity of factors that cause a painful experience. Some, such as endoscopist skill and anatomical differences between the sexes in the sigmoid colon are likely colonoscopy specific, while anxiety-related pain perception may apply to both modalities.[45] The requirement for onward investigation does not explain the differences in reported perception of procedural pain. Sedo-analgesia levels at colonoscopy were not recorded but, since this was an NHS E study conducted during the COVID-19 pandemic, it is unlikely that any patients had a general anaesthetic to support their colonoscopy. The anticipation of pain is consistent with the observations on preprocedural preferences for alternative procedures.

Bowel preparation was equally onerous for patients having CCE and colonoscopy. This is unsurprising since the bowel preparation was the same or similar. However, significantly more patients having CCE (19% vs 8% colonoscopy patients and yet 14% for those having CTC) felt that the bowel preparation would put them off having a repeat procedure in future, a finding that is largely driven by women's experiences. This finding is not wholly explainable by the need for onward colorectal investigations. While 52% of patients having CCE went on to a further investigation compared with 34% who had CTC and 16% colonoscopy, the onward investigation rates

were equivalent across the sexes. Perhaps some during the pilot may have hoped the bowel preparation for CCE would be less burdensome than that for colonoscopy and so had unrealistic expectations. Alternatively, since it was arguably the only unpleasant element of the CCE investigation, bowel preparation may have assumed greater significance in the mind of the patient. A first booster was taken by 88% of CCE patients and a second by 76% followed by a suppository in 41%. The duration of the CCE may be a factor, noting that CCE patients were more likely to be put off when a second booster and/or suppository was required. Perhaps these additional procedural elements contributed to the way patients reflected on their bowel preparation experience, although the booster experience was explored separately from bowel preparation in the questionnaire (online supplemental appendix C1). Should bowel preparation truly be more challenging for women having CCE, it may explain the significant differences in procedural satisfaction seen between men and women (75% vs 54%).

Beyond the preprocedural and procedural challenges, 'conclusivity' is key to the effectiveness of these investigative modalities. Patient satisfaction was 87% when CCE was conclusive. The findings of the logistic regression analysis confirm that while colonoscopy was painful, it tended to be conclusive and so provided diagnostic reassurance. As a result, patients were confident that colonoscopy was the right procedure for them. By contrast, the lack of conclusivity after CCE was the discriminating factor in predicting patient satisfaction between CCE and colonoscopy. This 'colonoscopy closure' also likely explains the shift in preprocedural (with almost two times as many patients having a colonoscopy than a CCE initially expressing a preference for an alternative investigation) to postprocedural satisfaction in favour of colonoscopy over CCE.

## Existing evidence

To date, the SCOTCAP programme included a mixed methods process evaluation involving a survey of over 200 patients who underwent CCE, finding that over 80% would recommend the service to others.[6] Their findings, like ours, highlight the importance of clear and accessible information, although as their patient group is largely based in the Highlands of Scotland, their focus was on travel time, reducing waiting times and home procedure completion.

Our procedural patient experience findings also mirror those of a study of the Danish bowel screening programme with patients who underwent consecutive CCE and colonoscopy.[9] Here, unlike colonoscopy, CCE was associated with no or minor pain and no embarrassment.

## Strengths and limitations

Our study has the advantage of comparing CCE, colonoscopy and CTC and CCE through the whole investigative journey. It was though a retrospective survey, asking participants to reflect on their experiences, sometimes after approaching 2 years. This was an inevitable consequence of securing funding and approvals for the study once the NHS E pilot had been established. Recollection bias is a clear risk when considering the data, however there are some sense-checks within the survey that provide reassurance, such as the 90% response rate for recalling the first CCE booster. We believe that setting context within the questionnaire was helpful and explains, for example, the interesting differences between the reported preprocedural and postprocedural preferences.

Patients undergoing CTC were included in the survey because it too is a diagnostic modality and, since as a 'filter test' it performs a similar role to CCE, we judged that it may provide additional comparative insights for those who undergo a purely diagnostic colorectal investigation on the understanding that an onward therapeutic intervention may be required. The small numbers of recruits who had CTC reflects the challenges of conducting this study during the COVID-19 pandemic. The 48% survey response rate, we judge to be acceptable; however, possible selection bias could not be excluded from what was a pragmatic study design, which aimed to recruit all available eligible patients from within an existing service evaluation. Any future validation of patient experience measures would need to be much more representative in terms of health equality, diversity and inclusivity across NHS E.

The questionnaire was developed to support the assessment of patient experience during the NHS E pilot by an expert panel and was revised in response to patient feedback using a 'think aloud' process. Accepted frameworks were used to develop the questionnaire, which we would hope could be refined and validated in future. Currently, no validated and approved CCE survey exists, although we used some questions from the validated GESQ. The study particularly demonstrates that, since CCE is a novel technology, it requires a specific set of patient-facing standards, guidelines and information provision. The quality of these standards could be benchmarked against the common experiences with those having colonoscopy and CTC.

Although emerging data support its diagnostic accuracy, CCE is currently an undefined colorectal diagnostic technology. Noting that the study took place following the rapid introduction of CCE, established during the COVID-19 pandemic, it is perhaps unsurprising that more patients had concerns about its effectiveness and safety than that of colonoscopy and CTC. While NHS England provided guidance on patient selection, it was for each participating site to develop its own clinical service within a guidance framework. Supportive patient and clinician CCE information was provided by NHS E and Medtronic to each site. For the future, this might be improved on and, anecdotally, a number of sites generated their own accompanying information materials and support service.

### Interpretation and generalisability

CCE does not appear to provide a simple solution for those who struggle with colonoscopy. The lack of pain for most who have CCE provides an opportunity to reimagine colorectal diagnostic services for the future. But patients in our study felt less well-informed about CCE compared with colonoscopy. Tailored, high-quality information to support the patient through all stages of the CCE journey is essential. 28% of patients who had CCE called their hospital team during the procedure, presumably because of uncertainty relating to the process. CCE can take many hours and a patient may feel isolated, anxious or afraid during this time. We were unable in this study to draw any absolute associations between CCE duration and the individual patient experience although there was some evidence relating to the use of a second booster and/or suppository. While age or sex did not predict for CCE satisfaction per se, women did find that the bowel preparation experiences were sufficiently difficult for 30% of them to be put off having a future CCE. Adequate bowel preparation is a key element in ensuring a high-quality CCE. Half of those patients who went on to further colorectal investigations did so because the CCE was incomplete or inadequately prepared. It is, therefore, essential that the patient is provided with sufficient information to help them understand the importance and possible challenges of rigorous bowel cleansing and be able to commit to it. For the future, CCE delivery could move much closer to home. In this survey, 98% of patients had their CCE at hospital. A home-based service may make CCE a much more tolerable procedure as the SCOTCAP programme found.[6] However, it is the need for onward investigation, whatever the cause, that clearly influences the utility of CCE as a filter test within an expanded colorectal diagnostics service, and which predicts patient satisfaction.[26] Patients should be aware that commensurate onward investigation, including colonoscopy, may be required should pathology or a need for further diagnosis be identified. In this way, better informed and engaged patient selection for CCE may be achieved. Reassuringly, there was little postprocedural anxiety in CCE patients despite the inevitable delay in getting the test results. Fewer patients felt that CCE had been the right test for them compared with those undergoing colonoscopy or CTC, which may reflect the fact that over half of our CCE respondents required further bowel investigations. This reinforces the need for shared decision-making and careful patient selection at the outset, which should be informed by future research.

Individualised information and a holistic approach are required for patients to make an informed decision about which procedure is right for them. This should also include considerations around their performance status or comorbidities, their age, laboratory findings and their sex. These all may affect either the likelihood of an adequate bowel preparation and the risk of finding pathology that requires onward intervention.

## CONCLUSIONS

CCE is similarly or better tolerated than colonoscopy and CTC throughout the patient journey. The CCE procedure is significantly less painful than the other modalities. Most patients were satisfied with their chosen investigation, whichever it was, and there was less certainty among those having a CCE that it had been the right test for them.

This study provides evidence to inform improvements to patient experience, particularly the need for appropriate patient selection to increase the likelihood of a conclusive index investigation, improved information and support. This will be key to the development of patient-facing and patient-engaged CCE diagnostic clinical services for the future. It is our hope that the findings from this study will inform the development of Patient Related Experience Measures and improved information provision in that future service.[46]

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