

An evaluation of the safety, efficacy and feasibility of “at-home” capsule endoscopy

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- **Figure: 1**
- **Table: 1**
- **Patients self-reported questionnaire**

ABSTRACT

Objective

The role of small bowel capsule endoscopy in diagnosing gastrointestinal diseases has long been established. Recently, colon capsule endoscopy has been suggested as an alternative to colonoscopy. CE has been traditionally conducted at Endoscopy units. However, during the Covid-19 pandemic, a switch was made to "at-home capsule endoscopy" (ACE) which has continued to date. This study is an evaluation of ACE, focusing on safety, efficacy, feasibility, and patient perceptions.

Methods

The study evaluated the performance of ACE in 105 consecutive patients, considering procedure outcomes, completion rates, complications, and patient satisfaction. Self-report questionnaires were used to assess perceptions and preferences from 84 ACE patients and 43 in-hospital CE patients. ACE procedure involved pre-assessment calls, bowel preparation, equipment setup, virtual verbal consent, capsule ingestion, booster alerts, and equipment collection. Descriptive statistics and tests of independence were used for data analysis.

Results

All 105 ACE patients were able to have CE at home, with completion rates for SBCE, CCE, and PCCE at 98.3%, 75.9%, and 55.6%, respectively. Patients reported low levels of pain (94.1%), embarrassment (98.8%), and anxiety (82.1%). ACE saved time and money, as 42.9% of patients were able to avoid work absence and 65.5% avoided transportation costs. ACE patients reported high satisfaction with the overall procedure (mean=8.5, SD=1.9), and 83.3% would prefer CE again at home.

Conclusion

This study demonstrates that at-home CEs are clinically effective and well-received by patients, providing the opportunity to conduct the test in the comfort of patients' homes.

Keywords: colonoscopy; capsule endoscopy; at-home capsule endoscopy (ACE); patients' satisfaction; feasibility; safety; efficacy; COVID-19

KEY MESSAGES

What is already known on this topic

- Small bowel CE (SBCE) has been consistently used for investigation of small bowel pathology. Panenteric (Crohn's) capsule endoscopy (PCCE) is an innovative tool for investigating both the small and large intestines.
- Colonoscopy is the gold standard for diagnosing colorectal cancer (CRC), but it is invasive and resource intensive. Colon capsule Endoscopy (CCE) conducted at Endoscopy Hospital units has been reported as a non-invasive alternative to triage symptomatic patients.

What this study adds

- "At-home capsule endoscopy" (ACE) is an opportunity for entirely remote GI diagnostics of the small and large bowel. It is a feasible procedure with no additional safety concerns than the traditional CE.
- Patients were satisfied with the ACE procedure, and they perceived the ACE as more convenient and cost-effective.

How this study might affect research, practice or policy

- Advancing the development of ACE could be greatly advantageous for increasing CE uptake, particularly in certain groups who face difficulties with conventional in-hospital investigations, such as colonoscopy.

INTRODUCTION

The role of SBCE and its high sensitivity in identifying small bowel pathology has well been established, and particularly in patients with Crohn's disease, it may identify active inflammation when previous imaging tests have been normal and can result in change of management in up to half of patients (1). PCCE is a novel diagnostic tool which has shown superior sensitivity and specificity in diagnosing active Crohn's disease compared to traditional ileocolonoscopy and MR enterography (2). CCE has been proposed as a way to reduce demand for colonoscopy for symptomatic patients with a positive Faecal Immunochemical Test (FIT) (3-7). Colonoscopy is the gold standard test for diagnosing or preventing CRC, but it has disadvantages such as invasiveness, risks of complications, and resource intensity (8-10).

CE involves the patients swallowing a battery-powered capsule containing a small camera which captures images of the gastrointestinal tract (11). Throughout the procedure, patients are required to wear a belt with a data recorder (12) while continuing their daily activities as usual. CE is perceived as a more comfortable and less embarrassing procedure compared to colonoscopy (13). Both CCE and PCCE require bowel preparation, while SBCE may or not involve laxatives. CCE/PCCE require a longer preparation period and a booster pack of laxatives to propel the capsule (14). CCE has shown comparable accuracy to colonoscopy for polyp detection and is a useful tool for CRC screening (15,16). NHS England has allocated funding for CCE implementation, and Scotland's Scotcap project is evaluating its utility and economic benefits (17).

During the Covid-19 pandemic, an "at-home capsule endoscopy" (ACE) was developed by University College London Hospital (UCLH), allowing patients to complete all types of different capsule endoscopies entirely remotely with virtual assistance. Pillcam SB3, Pillcam Colon2 and Pillcam Crohn's capsules (manufactured by Medtronic) were used throughout the study.

Data were collected prospectively to evaluate the safety and feasibility of this innovative approach. Specifically, we assessed the proportion of patients who would be competent to conduct the CE entirely remotely with no need to attend the hospital at any occasion and the number of significant capsule related adverse events (e.g., capsule retention or aspiration). Furthermore, we gathered data on ACE completion and insights into patient satisfaction with the procedure as a secondary endpoint.

MATERIALS AND METHODS

Patients and setting

Between March 2021 and February 2022, shielding patients or patients who avoided attending the hospital due to fear of Covid-19 were offered an ACE. Subsequently patients within a certain distance from the hospital were routinely offered ACE with the exception to individuals 1) classified as morbidly obese (BMI 40 or higher which would require the use of a sensor array rather than the belt); 2) lack of IT infrastructure; 3) unable to complete the test from home independently or had no relative that could assist them; and 4) capsule contraindications (e.g., pregnant, strictures, obstructive symptoms, and swallowing difficulties). The specified distance of patients' home from the hospital was decided upon courier cost which was agreed not to overcome £50 return. Patients who had the ACE procedure between March 2021 and June 2022 were included in this analysis, yielding a sample of 105 patients out of a total number of 387 CEs conducted in this time period. ACE was an innovation within the NHS and data were collected prospectively primarily for auditing and service improvement purposes.

ACE Methodology

Patients were sent an information video which explained the procedure and demonstrated the steps for applying the equipment prior to capsule ingestion (18). If they chose to proceed, they had a pre-assessment call with endoscopy staff a week before their procedure. Staff confirmed pre-procedure steps and checked that the patient had received the regime to prepare their bowel (Figure 1).

<Insert Figure 1>

Pre-procedure preparation. Preparation for SBCE included fasting the day before except for a light breakfast and low fibre diet 5 days prior to the test. Patients who had a previously failed procedure or known slow gut transit, were instructed to take 2-L polyethylene glycol as split dose prep the evening before and morning of the procedure and one tablet of metoclopramide on capsule swallow. Patients having CCE/PCCE followed the detailed bowel prep and post capsule ingestion regime as shown in Figure 2 (see supplementary material 1). Towards the end of the trial Metoclopramide was replaced by Prucalopride. The day before the procedure, a courier delivered the equipment to the patient along with a patient questionnaire.

Day of the procedure. On the day of the ACE, a scheduled video call using the 'Attend Anywhere' application allowed consent to be taken verbally. The signed consent form was returned along with the recording device, and instructions were given about how to attach the recorder and the belt. The patient then swallowed the capsule whilst on the call. Patients who had a CCE/PCCE received up to three alerts from the device to remind them about the boosters (see supplementary materials 1). To ensure the capsule has passed in the GI tract, the patient was asked to turn the recorder to 'real-time viewer' for a few minutes while member of staff was watching on the screen. The excreted capsule was disposable in the toilet. In the event of capsule aspiration, patients would be advised to come directly to the UCLH Endoscopy department for an endoscopic capsule retrieval. The rest of the equipment was collected by a courier the next day after the procedure along with the completed questionnaire.

Outcome measures for the ACE procedure. Data covered patients' age and gender, diagnostic modality, quality of bowel preparation, ability to perform the procedure at home, completion rates, complication rates and findings. For SBCE, completion was defined as capsule reaching the caecum before the battery ended. For CCE/PCCE, completion was defined as the capsule seen excreted via the anus. The quality of bowel preparation for the CCE/PCCE was measured using the CC-CLEAR score and for the SB3 was categorised as 'poor-fair-good-excellent', by a nurse and a consultant.

Measures

Both remote and hospital CE patients were asked to fill out an anonymous questionnaire about their experience and satisfaction from the procedure. The questionnaires were given between April 2021 and June 2022, and 127 patients provided responses, comprising of 84 ACE and 43 patients having CE on-site.

Most questions featured five-point Likert response options ("to a very small extent" until "to a very large extent"), while patients' satisfaction of the procedure was measured using a scale from 1 to 10. Patients were further asked to indicate their future most preferable investigation for their bowel. Additionally, ACE patients were asked about taking time off work for the procedure, as well as their distance from

the hospital, way and cost of travel if they would have had the test on-site (see supplementary material 2 for the full version of the questionnaire).

Sample size and data analysis

Due to the exploratory nature of the study, no formal sample size was calculated beforehand. Characteristics of the study sample were described using descriptive statistics. Due to the low frequencies in some categories, the answers to all perception questions were collapsed into two categories (“to a very small extent”, “to a small extent” and “somewhat” vs. “to a large extent” and “to a very large extent”). Chi-Square tests of independence and Fisher’s exact tests were used for categorical variables in the univariate analyses. Statistical significance was accepted at $p \leq 0.05$. Statistical analysis was conducted with Stata version 16.0 (StataCorp LP, College Station, TX).

RESULTS

ACE procedure data

Sample characteristics

Between April 2021 and June 2022, 105 ACE procedures were conducted. On average, patients were 39 years old (SD=15.2), with 56.2% being females. Approximately half of the patients had a SBCE (55.2%), followed by CCE (27.6%) and PCCE (17.1%). The majority of patients had the procedure for suspicion of Inflammatory Bowel Disease (IBD) (37.1%) or for IBD re-assessment (30.5%). Other indications were anaemia, positive FIT, change in bowel habit, polyp surveillance and previous gastrointestinal bleed (see Table 1).

Table 1. Demographic characteristics of study participants (N=105).

| | N | % |
|--|----|------|
| Age (mean, SD) | 39 | 15.2 |
| Age category | | |
| Below 18 | 3 | 2.9 |
| Between 18 and 29 | 29 | 27.6 |
| Between 30 and 39 | 25 | 23.8 |
| Between 40 and 49 | 25 | 23.8 |
| Between 50 and 59 | 12 | 11.4 |
| 60 or older | 11 | 10.5 |
| Gender | | |
| Male | 46 | 43.8 |
| Female | 59 | 56.2 |
| Diagnostic modalities | | |
| Small Bowel Capsule Endoscopy (SBCE) | 58 | 55.2 |
| Colon Capsule Endoscopy (CCE) | 29 | 27.6 |
| Pan-enteric Crohn's Capsule Endoscopy (PCCE) | 18 | 17.1 |
| Procedure investigation | | |
| Pil-cam Colon Capsule (PCC) Endoscopy (CCE+PCCE) | 47 | 44.8 |
| Small Bowel Capsule Endoscopy (SBCE) | 58 | 55.2 |
| Indication | | |
| Inflammatory Bowel Disease suspicion (IBD) | 39 | 37.1 |
| IBD Re-assessment | 32 | 30.5 |
| Iron deficiency anaemia | 11 | 10.5 |
| Positive FIT test | 10 | 9.5 |
| Change in bowel habit | 7 | 6.7 |
| Surveillance | 4 | 3.8 |
| Gastrointestinal bleeding | 2 | 1.9 |

Main findings

All 105 patients (100%) successfully swallowed the capsule at home without any need for 'at-hospital' conversion of the procedure. One patient who had CCE visited the emergency department complaining of abdominal pain a day post procedure, but a CT scan was normal and the capsule had been excreted. Three patients vomited the bowel preparation. There were no complications of capsule retention or aspiration nor any other significant adverse events.

57 (98.3%) SBCE procedures were complete, as opposed to 22 (75.9%) CCE and 10 (55.6%) PCCE. The observed quality of preparation for PCCE/CCE was regarded as excellent (35.3%) and good (47.1%) with a mean CC-CLEAR score of 6.6 out of 9 (median 7.0). Failed preparation was observed among 20.7% of CCE patients, 16.7% of PCCE and 5.2% of SBCE. Almost 45% of PCCE patients had an incomplete procedure which was significantly higher ($p<0.001$) compared to SBCE (1.7%) and CCE (24.1%).

Among 47 patients who had CCE/PCCE, the clinical question was satisfied by the results of the ACE for 78.7% of the patients, hence no further investigations were needed. Only 10 patients (21.3%) who had CCE/PCCE needed a follow-up colonoscopy.

The outcome of the ACE was normal in 43.8% of patients. Normal findings were substantially lower for PCCE (33.3%) compared to SBCE and CCE (43.1% and 51.7% respectively). PCCE had the highest rates of inflammation (50%). The rest of pathology according to the capsule ingested is shown in detail in Table 2.

Table 2. Characteristics of the procedure by diagnostic modality (N=105).

| | Small Bowel Capsule Endoscopy (SBCE) N=58 | | Colon Capsule Endoscopy (CCE) N=29 | | Pan-enteric Chron's Capsule Endoscopy (PCCE) N=18 | | Total (N=105) | | p-value* |
|--|---|------|------------------------------------|------|---|------|---------------|------|----------|
| | N | % | N | % | N | % | N | % | |
| Bowel preparation taken | | | | | | | | | |
| No | 44 | 75.9 | 3 | 10.3 | 1 | 5.6 | 48 | 44.8 | <0.001 |
| Yes | 14 | 24.6 | 26 | 89.7 | 17 | 94.4 | 57 | 55.2 | |
| Quality of preparation | | | | | | | | | |
| Numeric (mean, SD) | - | - | 6.5 | 2.5 | 6.9 | 1.7 | 6.6 | 2.2 | 0.904 |
| Category | | | | | | | | | |
| Poor | - | - | 5 | 23.8 | 1 | 7.7 | 6 | 17.7 | 0.374 |
| Good | - | - | 8 | 38.1 | 8 | 61.5 | 16 | 47.1 | |
| Excellent | - | - | 8 | 38.1 | 4 | 30.7 | 12 | 35.3 | |
| Failed preparation | | | | | | | | | |
| No | 55 | 94.8 | 23 | 79.3 | 15 | 83.3 | 93 | 88.6 | 0.065 |
| Yes | 3 | 5.2 | 6 | 20.7 | 3 | 16.7 | 12 | 11.4 | |
| Capsule passed into caecum/excreted | | | | | | | | | |
| No | 1 | 1.7 | 7 | 24.1 | 8 | 44.4 | 16 | 15.2 | <0.001 |
| Yes | 57 | 98.3 | 22 | 75.9 | 10 | 55.6 | 89 | 84.8 | |
| Failed procedure | | | | | | | | | |
| No | 55 | 94.8 | 20 | 68.9 | 9 | 50 | 84 | 80 | <0.001 |
| Yes | 3 | 5.2 | 9 | 31.0 | 9 | 50 | 21 | 20 | |
| Procedure time | | | | | | | | | |
| Median, range | 5 | 1-13 | 5.6 | 2-17 | 8 | 2-16 | 5 | 1-17 | 0.038 |
| Complications | | | | | | | | | |
| No | 58 | 100 | 27 | 93.1 | 16 | 88.9 | 101 | 96.2 | 0.033 |
| Yes | 0 | 0 | 2 | 6.9 | 2 | 11.1 | 4 | 3.8 | |
| Followed up by Colonoscopy | | | | | | | | | |
| No | 42 | 72.4 | 23 | 79.3 | 14 | 77.8 | 79 | 75.2 | 0.001 |
| Yes | 0 | 0 | 6 | 20.7 | 4 | 22.2 | 10 | 9.5 | |
| Missing | 16 | 27.6 | - | - | - | - | 16 | 15.2 | |
| Clinical findings | | | | | | | | | |
| Normal | 25 | 43.1 | 15 | 51.7 | 6 | 33.3 | 46 | 43.8 | 0.043 |
| Inflammation | 23 | 39.7 | 5 | 17.2 | 9 | 50 | 37 | 35.2 | |
| Angiodysplastic lesions | 7 | 12.1 | 2 | 6.9 | 1 | 5.6 | 10 | 9.5 | |
| Polyps | 3 | 5.2 | 3 | 10.3 | 0 | 0 | 6 | 5.7 | |
| Diverticular disease | 0 | 0 | 2 | 6.9 | 2 | 11.1 | 4 | 3.8 | |
| Angiodysplastic lesions and polyps | 0 | 0 | 1 | 3.5 | 0 | 0 | 1 | 1 | |
| Angiodysplastic lesions and diverticular disease | 0 | 0 | 1 | 3.5 | 0 | 0 | 1 | 1 | |

* p-value refers to Fisher's exact test

Patient-reported experience data

Sample characteristics

A total of 127 satisfaction questionnaires were completed. Of these, 84 patients (66.1%) had ACE. On average, patients were 40 years old (SD=15.9, range 15-85), with 60.6% being females. Most patients (n=108) had experience of previous GI investigation (71.7% colonoscopy, 13.4% CTC). There were no differences in age, gender and previous procedures between patients that had the procedure on-site and remotely (see supplemental material 3).

Main findings

Patient reported experience and satisfaction from the ACE. The results were summarised in Table 3. Almost 95% patients reported that they received sufficient support from the hospital staff to conduct the test at home. Most were also satisfied with completing the test at home (79.8%), and they would repeat the procedure at home (83.3%).

42.9% of ACE patients were able to work as normal on the day of the test, while 5 respondents (5.9%) took a half day off and 26 respondents reported (31%) taking a full day off work. Most respondents said that they would have had to take a full day off at work to do the test in the hospital (48.8%) and would have spent up to £10 or more to get to the hospital and back (52.4%). ACE patients scored the procedure as 8.5/10 (see Table 4).

Table 3. Satisfaction and opportunity costs associated with remote procedure (N=84).

| | N | % |
|--|----|------|
| <i>Satisfaction with remote procedure</i> | | |
| Received support from the hospital to do the test at home | | |
| To a very small extent/ To a small extent/Somewhat | 4 | 4.8 |
| To a large extent/ To a very large extent | 79 | 94.1 |
| Missing answer | 1 | 1.2 |
| Satisfied with procedure at home | | |
| To a very small extent/ To a small extent/Somewhat | 13 | 15.5 |
| To a large extent/ To a very large extent | 67 | 79.8 |
| Missing answer | 4 | 4.8 |
| Where would you do the test again | | |
| At home | 70 | 83.3 |
| In the hospital | 7 | 8.3 |
| Missing answer | 7 | 8.3 |
| <i>Impact of the procedure on working and travel time</i> | | |
| Took time off work for the procedure | | |
| No | 36 | 42.9 |
| Yes, half day | 5 | 5.9 |
| Yes, full day | 26 | 31 |
| Missing answer | 17 | 20.2 |
| How would you have gone the procedure in the hospital? | | |
| Own or family car | 13 | 15.5 |
| Taxi | 5 | 6 |
| Public service | 37 | 44.1 |
| Walk | 2 | 2.2 |
| Missing answer | 27 | 32.1 |
| One-way distance to the hospital (in Km) | | |
| Up to 10 km | 25 | 29.8 |
| More than 10 km | 18 | 21.4 |
| Missing answer | 41 | 48.8 |
| Cost of traveling to the hospital and back home (in £) | | |
| £ 0 | 4 | 4.8 |
| £1 - 10 | 26 | 31 |
| More than £ 10 | 18 | 21.4 |
| Missing answer | 36 | 42.9 |
| Would you have taken time off work to do the test in the hospital? | | |

| | | |
|----------------|----|------|
| No | 17 | 20.2 |
| Yes, half day | 4 | 4.8 |
| Yes, full day | 41 | 48.8 |
| Missing answer | 22 | 26.2 |

Comparison with CE at the Hospital. Most responses were similar between the ACE patients and the patients on-site (see Table 4). The rates of anxiety in ACE compared to conventional CE were numerically lower but this difference was not statistically significant (16.7% vs 25.6%, $p=NS$). There were low levels of pain and anxiety in both groups.

Patients were asked which type of investigation they would prefer in the future for investigation of their bowel, with particular emphasis in the lower GI tract. This was because we wanted to explore a potential preference of ACE against the usual on-site GI investigations, i.e. colonoscopy. Furthermore, we were aware that 71.7% of the cohort patients had previously had the experience of a colonoscopy (see supplementary material 3), making them a valid sample for comparison. Patients who had capsule remotely were more likely to choose ACE compared to any other test (61.9%). By contrast, only 27.9% of the CE patients who had the test at the hospital would choose to have CE again at the hospital, suggesting that the actual home element might provide an additional advantage.

Table 4. Patients reported experience and satisfaction of the procedure (N=127).

| | Where was the procedure done | | | | | | p-value* |
|--|------------------------------|------|--------------------|------|------------------|------|----------|
| | Remote (N=84) | | Hospital (N=43) | | Total (N=127) | | |
| | N | % | N | % | N | % | |
| Information sufficient to explain procedure | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 19 | 22.6 | 6 | 14 | 25 | 19.7 | 0.22 |
| To a large extent/ To a very large extent | 65 | 77.4 | 36 | 83.7 | 101 | 79.5 | |
| Missing answer | 0 | 0 | 1 | 2.3 | 1 | 0.8 | |
| Staff could resolve queries | | | | | | | |
| No | 6 | 7.1 | 1 | 2.3 | 7 | 5.5 | 0.492 |
| Yes | 47 | 56 | 28 | 65.2 | 75 | 59.1 | |
| No queries | 31 | 37 | 14 | 32.6 | 45 | 35.4 | |
| Wait for the procedure to be booked | | | | | | | |
| No | 76 | 90.5 | 36 | 83.7 | 112 | 88.2 | 0.403 |
| Yes | 6 | 7.1 | 6 | 13.4 | 12 | 9.5 | |
| Missing answer | 2 | 2.4 | 1 | 2.3 | 3 | 2.4 | |
| Not known what to expect of the test | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 14 | 16.7 | 8 | 18.6 | 22 | 17.3 | 0.785** |
| To a large extent/ To a very large extent | 70 | 83.3 | 35 | 81.4 | 105 | 82.7 | |
| Anxious about procedure | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 69 | 82.1 | 32 | 74.4 | 101 | 79.5 | 0.441 |
| To a large extent/ To a very large extent | 14 | 16.7 | 11 | 25.6 | 25 | 19.7 | |
| Missing answer | 1 | 1.2 | 0 | 0 | 1 | 0.8 | |
| Difficulties tolerating the cleansing preparation | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 33 | 39.3 | 16 | 37.2 | 49 | 38.6 | 0.302 |
| To a large extent/ To a very large extent | 14 | 16.7 | 12 | 28 | 26 | 20.5 | |
| Missing answer | 37 | 44.1 | 15 | 34.9 | 52 | 40.9 | |
| Was capsule too big to swallow | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 78 | 92.9 | 38 | 88.4 | 116 | 91.3 | 0.335 |
| To a large extent/ To a very large extent | 6 | 7.1 | 4 | 9.3 | 10 | 7.9 | |
| Missing answer | 0 | 0 | 1 | 2.3 | 1 | 0.8 | |
| Was procedure painful | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 79 | 94.1 | 38 | 88.4 | 117 | 92.1 | 0.444 |
| To a large extent/ To a very large extent | 2 | 2.4 | 3 | 7 | 5 | 3.9 | |
| Missing answer | 3 | 3.6 | 2 | 4.7 | 5 | 3.9 | |
| Was procedure embarrassing | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 83 | 98.8 | 39 | 90.7 | 122 | 96.1 | 0.061 |
| To a large extent/ To a very large extent | 0 | 0 | 2 | 4.7 | 2 | 1.6 | |
| Missing answer | 1 | 1.2 | 2 | 4.7 | 3 | 2.4 | |

| | | | | | | | |
|--|-----|------|----|------|-----|------|----------|
| Was procedure tiring | | | | | | | |
| To a very small extent/ To a small extent/Somewhat | 49 | 58.3 | 27 | 62.8 | 76 | 59.8 | 0.339 |
| To a large extent/ To a very large extent | 34 | 40.5 | 14 | 32.6 | 48 | 37.8 | |
| Missing answer | 1 | 1.2 | 2 | 4.65 | 3 | 2.4 | |
| What test would you prefer in the future | | | | | | | |
| Colon capsule at home | 52 | 61.9 | 4 | 9.3 | 56 | 44.1 | <0.001 |
| Colon capsule in hospital | 2 | 2.4 | 12 | 27.9 | 14 | 11 | |
| Colonoscopy | 13 | 15.5 | 4 | 9.3 | 17 | 13.4 | |
| CT colonography | 3 | 3.6 | 1 | 2.3 | 4 | 3.2 | |
| Other | 2 | 2.4 | 4 | 9.3 | 6 | 4.7 | |
| Unsure | 3 | 3.6 | 1 | 2.3 | 4 | 3.2 | |
| Missing answer | 9 | 10.7 | 17 | 39.5 | 6 | 20.5 | |
| Satisfaction score [1-10] | | | | | | | |
| Mean and SD | 8.5 | 1.9 | 8 | 2.8 | 8.4 | 2.2 | 0.231*** |

* p-value refers to Fisher's exact test ** p-value refers to Chi-Square test *** p-value refers to Student t-test

DISCUSSION

ACE is an innovation which was originally initiated due to the COVID-19 pandemic. To our knowledge, no prior study has investigated the at-home capsule endoscopy. Although NHS Scotland has launched the Scotcap project to provide CCEs remotely, this was done in community centres and district general hospitals with physical supervision from trained nursing staff (17), as opposed to ACE which requires patients to apply the equipment independently at home.

A potential alternative home delivery system exists, Capsocam, this does not involve the use of wireless belt, antenna and recorder and the data is all stored in the capsule itself. With this system, the patient needs to collect the capsule from the toilet with the use of a magnetic 'fishing' wand (19). Anecdotally, most of our patients have shown to be reluctant to use Capsocam because of the requirement to retrieve the capsule from the faeces. Moreover, this system only manufactures small bowel capsules.

All ACE patients achieved the procedure without a single individual abandoning and converting to CE on-site. They were able to independently wear the belt, pair the capsule with the recorder and swallow the capsule with staff assistance being provided only via video call. There were no safety concerns and adverse events were similar to what is expected from traditional CE. Those results suggest an opportunity for entirely remote GI diagnostics without increasing the fear or risk of complications.

Although this is not a comparator study, the quality and completion rates of the ACE procedures is similar to what is recorded in published literature for traditional CE which is conducted in hospitals. Our SBCE at-home capsules, albeit a small overall number, were almost 100% complete, suggesting adherence to the key performance indicators by the European Society of Gastrointestinal Endoscopy (ESGE), where caecal visualisation should be achieved in > 80% of SBCE procedures (20). The completion rates of CCE and PCCE were also similar to the published systematic review of 12 studies, between 57-100% (16), and the national NHS England CCE pilot programme (21). Towards the end of the study, metoclopramide was replaced by prucalopride which has since led to a significant improvement in completion rates of CCE/PCCE equally at on-site and at-home procedures (although this data is not included in this paper and in this particular cohort only 4 patients had prucalopride). Although PCCEs were associated with a lower completion rate compared to the other capsule types (55.6% vs 75.9% for CCE, 98.3% SBCE), subsequent comparisons in our prospective cohort data have not repeated this result, and considering the cleansing protocol for both colon and pan-enteric capsules is the same, we believe this difference was incidental.

The ACE procedure was well-received by patients, with a median life satisfaction score of 8.5/10 and accompanied by minimal reports of pain, embarrassment or anxiety. It seemed that patients who had ACE would prefer to have ACE in the future more compared to other GI investigations, and this preference appeared more prominent in the ACE group versus the on-site. We do, however, acknowledge that this was not a comparator study and selection bias may have affected the results, particularly within the hospital cohort. As this was an audit of a new service, ACE patients were strongly and repeatedly encouraged to fill out the satisfaction surveys, as opposed to the on-site cohort where the questionnaire completion was optional. This explains the significant difference in response rates between the two groups, highlighting the need for future prospective randomised studies to identify patients' preferences and differentiate to what extent the remote nature of the procedure provides additional advantages compared to conventional CE.

Similarly, as the focus was mainly on ACE's safety and feasibility, there was no comparison of procedure success or outcomes between the home and hospital groups, and this will need to be investigated further. The self-reported nature of our dataset resulted in substantial missing data for certain items. Due to the anonymity of the patient surveys, it was not possible to associate preferences with clinical or procedural factors (i.e., capsule type).

ACE could prove more cost-effective as patients save money but are also able to continue work as normal (half of the cohort). The courier cost is admittedly a barrier to using this service for patients who live further away from the hospital. However, with more widespread implementation the cost per patient of running the service would be reduced.

The ACE cohort's median age 39 years might be attributed to the common indication being Crohn's disease, which predominantly affects younger individuals. Additionally, the preference of ACE might be more pronounced among a younger population, possibly due to older patients' limited IT knowledge.

Implications for practice and research

The fact that ACE was feasible and safe introduces the opportunity to potentially implement CE in community centres and away from tertiary hospitals, which may have financial, ecological and other benefits that would need to be researched in the future. Increased patient acceptance of ACE could bring a more important role particularly for patients who refuse investigations at the hospital or busy professionals who do not want to miss time off work. Although this study does not compare ACE with colonoscopy, given the latter has proven problematic in patients' acceptance (22, 23), alternatives are welcome and the non-invasive a remote nature of ACE may present a promising avenue in reaching out to particular patient groups in the future.

Reading time of the captured images remains as a crucial challenge in the wider implementation of CE. Utilisation of artificial intelligence to alleviate the burden on human readers may set an entirely different scene for the use of CE in the near future.

CONCLUSION

This study shows the feasibility, safety and patient acceptance of fully remote diagnostic GI procedures through capsule endoscopy. Patients reported saving time and money, indicating so potential benefits over traditional GI investigations for both patients and the healthcare system.

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Authors contributions

CW, IP, and ES conceptualised the study. IP, SB, and AH acquired the data. SB, MN, and SS completed further analysis of the data contained within the manuscript. SB, MN, SS, IP, and AH jointly constructed initial and final drafts. AK, RK, ES, and CW reviewed the manuscript. All authors read and approved the final manuscript.

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Ethics Approval

No ethics approval.

Contributors and sources

Dr Ioanna Parisi is a Consultant Gastroenterologist and leads the Capsule Endoscopy Service at UCLH. Dr Ed Seward is a Consultant Gastroenterologist and Director of Endoscopy at UCLH. Dr Parisi and Dr Seward have conceptualised the idea of exclusively remote Capsule Endoscopy, designed and implemented the ACE pathway at appropriate UCLH patients during the Covid-19 pandemic. Dr Parisi designed the self-reported anonymous patient questionnaires, including relevant to the pathway questions but also questions routinely used in colonoscopy feedback surveys with associated published literature. Dr Sohail Badat is a clinical fellow at UCLH who helped in collection of patient data, demographics and survey responses. Prof. Christian von Wagner is a programme lead of the UCL MSc Health Psychology with research interest in early diagnosis of colorectal cancer. All the non-clinical authors are academicians who primarily contributed on writing the manuscript.

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Supplementary materials 1

| | |
|----------------------|--|
| Day before procedure | <p>19:00-21:00 - one bag of Moviprep® (sachets A and B) in one litre of water the night before the procedure</p> |
| Day of procedure | <p>06:00-08:00 - one bag of Moviprep® (sachets A and B) in one litre of water on the morning of the procedure</p> <p style="text-align: center;">↓</p> <p>Prucalopride 1mg table (or 2mg if history of constipation or used of medication which slow down the bowel)</p> <p style="text-align: center;">↓</p> <p>Swallow capsule</p> <p style="text-align: center;">↓</p> <p>Alert 1 – drink 30ml Phospho-soda® and 50ml Gastrografin® in a cup of water. Drink one litre of water over the next one hour.</p> <p style="text-align: center;">↓</p> <p>Alert 2 – drink 15ml Phospho-soda® and 50ml Gastrografin® in a cup of water. Drink 500ml of water over the next one hour.</p> <p style="text-align: center;">↓</p> <p>Alert 3 – insert one bisacodyl 10mg suppository if the capsule has not passed out.</p> <p style="text-align: center;">↓</p> <p>Alert 4 – you may eat a light meal</p> <p style="text-align: center;">↓</p> <p>End of procedure</p> |

Figure 1. Details of bowel preparation

Supplementary materials 2

PATIENT SATISFACTION FORM FOR CAPSULE ENDOSCOPY AT UCLH

You recently had a capsule endoscopy at UCLH. We would be grateful if you could take some time to answer a few questions below about your experience. This will help us improve the service and quality of care!

PRIOR TO THE PROCEDURE

1. Was the information you received sufficient to explain the procedure and resolve any queries you had?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

2. If not, were you able to contact a member of staff and resolve your queries?

Yes No

3. Were you anxious about having the procedure?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

4. Did you need to wait long for the procedure to be booked?

Yes No

BOWEL PREPARATION

5. Did you have difficulty in tolerating the bowel cleansing preparation instructed for you to take the day before and on the day of the procedure?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

6. If yes, which one of the medications you found more difficult to take and why?

Free text.....

DAY OF PROCEDURE

7. Did you know what to expect on the day of the test?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

8. Did you find the capsule too big to swallow?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

9. Did you find the procedure painful?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

10. Did you find the procedure embarrassing?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

11. Did you find the procedure tiring/ very long?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

OVERALL SATISFACTION

12. Have you ever had a colonoscopy (a test to investigate your lower bowel where a thin camera goes into the bowel through the back passage) before?

Yes No

13. Have you ever had a CT Colonography (a CT x-ray used to examine your lower bowel, whilst air is pumped into your back passage for insufflation) before?

Yes No

14. If needed in the future, which test would you prefer to have for examination of your bowel?

Colon Capsule Colonoscopy CT Colonography Other

Can you please tell us a bit more about why you would prefer this

test.....
.....
.....

15. Overall, how satisfied were you with your Colon (or pan-enteric) Capsule endoscopy?

1 (very dissatisfied) 2 3 4 5 6 7 8 9 10 (very satisfied)

16. Is there anything that you would like us to do to improve the Colon Capsule

Service.....
.....
.....

ABOUT YOU

17. Gender Male Female Other/ Prefer not to say

18. Age.....

19. Did you have a Small bowel, Colon or a Crohn's (Pan-enteric) capsule?.....

Thank you for your time!

PATIENT SATISFACTION FORM FOR A REMOTE (AT HOME) CAPSULE ENDOSCOPY

You recently had a capsule endoscopy at home. As this is a new service to the Department, we would be grateful if you could take some time to answer a few questions below about your experience. This will help us improve the service and quality of care!

PRIOR TO THE PROCEDURE

1. Was the information you received sufficient to explain the procedure and resolve any queries you had?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

2. If not, were you able to contact a member of staff and resolve your queries?

Yes No

3. Were you anxious about having the procedure?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

4. Did you need to wait long for the procedure to be booked?

Yes No

BOWEL PREPARATION

5. Did you have difficulty in tolerating the bowel cleansing preparation instructed for you to take the day before and on the day of the procedure?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

6. If yes, which one of the medications you found more difficult to take and why?

Free text.....

DAY OF PROCEDURE

7. Did you know what to expect on the day of the test?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

8. Did you have sufficient support from the UCLH capsule team to do this at home?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

9. Did you find the capsule too big to swallow?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

10. Did you find the procedure painful?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

11. Did you find the procedure embarrassing?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

12. Did you find the procedure tiring/ very long?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

13. Were you satisfied with the procedure done at home instead of the Hospital?

To a very large extent To a large extent Somewhat To a small extent To a very small extent

TRAVEL AND EXPENSES

14. Did you take time off work for the procedure?

No Yes, half a day off Yes, full day off

15. If the procedure was conducted at the hospital, how would you have got to the hospital?

Own/family car Voluntary care service Taxi Walk Public service (Bus, Underground, Train)

16. What is the approximate distance of the hospital (one-way) from home?

.....miles

17. How much would it have costed for you to get to the hospital and back?

£.....

18. If the procedure was conducted at the hospital, would you have taken time off work?

No Yes, half a day off Yes, full day off

OVERALL SATISFACTION

19. If you ever needed to have this procedure again, would you prefer to have it at home or at the Hospital?

_At home At Hospital

20. Have you ever had a colonoscopy (a test to investigate your lower bowel where a thin camera goes into the bowel through the back passage) before?

Yes No

21. Have you ever had a CT Colonography (a CT x-ray used to examine your lower bowel, whilst air is pumped into your back passage for insufflation) before?

Yes No

22. If needed in the future, which test would you prefer to have for examination of your bowel?

-Colon Capsule at home -Colon Capsule at Hospital -Colonoscopy -CT Colonography - Other

Can you please tell us a bit more about why you would prefer this

test.....
.....
.....

23. Overall, how satisfied were you with your Capsule endoscopy?

1 (very dissatisfied) 2 3 4 5 6 7 8 9 10 (very satisfied)

24. Is there anything that you would like us to do to improve the Service.....

.....
.....

ABOUT YOU

- 25. Gender Male Female Other/ Prefer not to say
- 26. Age.....
- 27. Did you have a Small Bowel, a Colon or a Crohn's (Pan-enteric) capsule?.....

Thank you for your time!

Supplementary materials 3

Table 5. Demographic characteristics of study participants (N=127).

| | Where was the procedure done | | | | | | p-value* |
|---|------------------------------|------|-----------------|------|---------------|------|----------|
| | Remote (N=84) | | Hospital (N=43) | | Total (N=127) | | |
| | N | % | N | % | N | % | |
| Age (mean, SD) | 40 | 14.7 | 40 | 18.2 | 40 | 15.9 | 0.109** |
| Age category | | | | | | | |
| Below 18 | 3 | 3.6 | 1 | 2.3 | 4 | 3.2 | 0.508 |
| Between 18 and 29 | 18 | 21.4 | 13 | 30.2 | 31 | 24.4 | |
| Between 30 and 39 | 23 | 27.4 | 9 | 20.9 | 32 | 25.2 | |
| Between 40 and 49 | 17 | 20.2 | 6 | 14 | 23 | 18.1 | |
| Between 50 and 59 | 12 | 14.3 | 4 | 9.3 | 16 | 12.6 | |
| 60 or older | 11 | 13.1 | 10 | 23.3 | 21 | 16.5 | |
| Gender | | | | | | | |
| Male | 31 | 32.6 | 14 | 32.6 | 45 | 35.4 | 0.432 |
| Female | 51 | 60.7 | 26 | 60.5 | 77 | 60.6 | |
| Missing | 2 | 2.4 | 3 | 7 | 5 | 3.9 | |
| Previous colonoscopy | | | | | | | |
| No | 20 | 23.8 | 15 | 34.9 | 35 | 27.6 | 0.339 |
| Yes | 63 | 75 | 28 | 65.1 | 91 | 71.7 | |
| Missing | 1 | 1.2 | 0 | 0 | 1 | 0.8 | |
| Previous CT colonography | | | | | | | |
| No | 69 | 82.1 | 37 | 86.1 | 106 | 83.5 | 0.843 |
| Yes | 12 | 14.3 | 5 | 11.6 | 17 | 13.4 | |
| Missing | 3 | 3.6 | 1 | 2.3 | 4 | 3.2 | |
| Self-reported small bowel colon or a Crohn's (pan-enteric) capsule | | | | | | | |
| No | 17 | 20.2 | 19 | 44.2 | 36 | 28.4 | 0.005 |
| Yes | 67 | 79.8 | 24 | 55.8 | 91 | 71.7 | |

* p-value refers to Fisher's exact test ** p-value refers to Chi-Square test