

Colon capsule endoscopy as possible filter test for colonoscopy selection in a screening population with positive fecal immunology

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Background and study aims: Stool tests are highly useful in colorectal cancer (CRC) screening programs; however, they are not as specific as users would like, and place a major burden on resources and subject a number of patients to the risks of invasive optical colonoscopy unnecessarily. Colon capsule endoscopy (CCE) has the potential to reduce the need for optical colonoscopy. To date, the role of CCE in a fecal immunological test (FIT)-based CRC screening program has not been formally evaluated. The aims of this study were to assess the sensitivity, specificity, and negative and positive predictive values of CCE compared with optical colonoscopy in an FIT-positive CRC screening cohort.

Patients and methods: A prospective comparison study of CCE compared with optical colonoscopy was undertaken within the second round of a FIT-based bowel screening pilot. Participants

with a positive FIT result were invited to undergo both CCE and optical colonoscopy. CCE was performed on Day 1 and optical colonoscopy was performed the following morning.

Results: A total of 62 participants were recruited. Optical colonoscopy detected at least one polyp in 36 participants (58%), significant lesions in 18 (29%), and cancer in 1 (2%). There was good correlation between CCE and optical colonoscopy for any lesion and for significant lesions ($r=0.62$ and 0.84 , respectively). The negative predictive value of CCE was high both for any polyp (90%) and for significant lesions (96%).

Conclusions: CCE is a safe and effective means of detecting cancer and polyps in a positive FIT screening cohort. The results suggest that CCE would be a useful “filter test” in this situation, and would reduce the number of colonoscopies performed by 71%.

Introduction

Colorectal cancer (CRC) is common in the developed world and is second only to lung cancer as the leading cause of death from cancer in Europe [1]. Although the results of treatment have shown a gradual improvement over the past 30 years, 5-year survival is still only about 50% in Ireland and the UK [2]. Randomized trials have shown that screening for bowel cancer using guaiac-based fecal occult blood tests (gFOBTs) can reduce mortality by 16% in people offered screening and 25% in those accepting the test [3, 4]. As a result, and in accordance with European recommendations, many countries have introduced or are introducing bowel cancer screening programs [5]. There are several screening models available. Along with the UK and other European Union countries, Ireland has adopted a two-stage population-based approach. In this model, individuals who are identified as at risk, by either gFOBT or fecal immunological test (FIT) occult blood tests,

are referred for invasive colonoscopy. However, while these tests select out a population at risk for colonic cancers and adenomas, the majority of individuals who undergo colonoscopy do not have neoplasia. Recent results from the UK in a study of gFOBT-positive participants, showed a neoplasia detection rate of 59.5% in men and 43.2% in women, and a CRC detection rate of 10.1% following further investigations [6]. FIT has been shown to be more sensitive and to produce higher overall positive rates compared with gFOBT [7]. A recent study from Spain on FIT and our own pilot showed similar neoplasia detection rates of 57% and 44%, respectively [8, 9]. These studies have demonstrated the usefulness of occult blood tests in screening, but the relatively high rate of false-positive tests is a concern. From the available data, at least 40% of people undergoing a screening colonoscopy following a positive FOBT will not have neoplasia detected, and therefore the procedure was unnecessary. In real terms, for every 1 million participants in the UK

screening program, no neoplasia was found in over 6000 colonoscopies performed. This represents a major burden on screening resources and a substantial risk for screening participants, due to the invasive nature of colonoscopy and the potential for significant, albeit infrequent, adverse events.

A model that reduces the negative colonoscopy rate would represent a major advantage over current strategies. One way may be to introduce a second “filter test” after FOBT; the test would have similar neoplasia detection rates to colonoscopy but lower risks. If effective, the filter test would select only those individuals with neoplasia for invasive standard colonoscopy, and the number of negative colonoscopies would therefore decline, reducing the burden on endoscopy services, staff, and participants.

Capsule endoscopy has been available for a number of years. Colon capsule endoscopy (CCE) with the PillCam (Given Imaging Ltd., Yoqneam, Israel) is an innovative, noninvasive, and painless ingestible capsule technique that allows exploration of the colon without the need for sedation and gas insufflation. The examination is easy to perform, can be done on an outpatient basis, and provides accurate views of the colon. Although initial reports were promising, two large early multicenter trials using the first-generation PillCam showed a low sensitivity for polyps [10, 11]. On this basis, the newer second-generation capsules were developed, with improvements that included a wider viewing angle and an adaptive frame rate to allow 36 frames per second on entering the colon.

Using these second-generation capsules, Spada et al. found a sensitivity of 84% for polyps larger than 6 mm [12]. Subsequent comparative studies with colonoscopy have reported a high degree of agreement, and suggest that capsule colonoscopy is useful in a variety of clinical settings, including symptomatic screening participants and after incomplete colonoscopy [13–16]. A recent European multicenter study reported sensitivities and specificities for larger polyps of 88% and 95%, respectively [17]. All studies reported a low complication rate for CCE and high levels of participant acceptance. Recently, the clinical indications for CCE and the reporting and work-up of detected findings have been standardized and published as a European Society of Gastrointestinal Endoscopy guideline [18].

To date, there have been no reports on the role of CCE in a FIT-based population CRC screening program. We propose that CCE could provide a screening filter test for people who have positive FIT results, thereby reducing the number of negative standard colonoscopies.

The aims of the current study were to prospectively assess the sensitivity, specificity and negative and positive predictive values of CCE compared with conventional optical colonoscopy in an FIT-positive CRC screening cohort.

Patients and methods

A prospective comparison study of CCE compared with the gold standard optical colonoscopy was undertaken. Ethical approval was granted to conduct this study within the second round of a local FIT screening pilot. In brief, 10 000 people aged 50–75 years from the local catchment area in Dublin were part of a biennial FIT-based CRC screening pilot. Participants were invited by letter to return a 2-day, two-sample FIT kit (OC-Sensor; Eiken Chemical Co., Ltd., Tokyo, Japan) as part of the pilot. Any single FIT result with a value above 100 ngHb/mL was considered to be positive,

and participants with a positive test were counseled by a screening nurse and invited for colonoscopy as per standard practice. During 1 year of screening, a number of study participants with a positive FIT result were invited to undergo both CCE and optical colonoscopy. Participants were selected at random and recruited by phone. Written informed consent was obtained from all participants. Participants were excluded if they had any of the following: a known or suspected small- or large-bowel stricture or obstruction, dysphagia, recent (6 weeks) abdominal surgery, significant renal impairment, a contraindication to bowel preparation, an allergy to any study medication, serious medical illness, or were unable to give informed consent. Participants’ demographics were recorded.

CCE was performed in accordance with the manufacturer’s guidelines on Day 1 and optical colonoscopy was performed the following morning on Day 2, as per the unit protocol. No additional bowel preparation was taken prior to optical colonoscopy.

Capsule colonoscopy procedure

A previously described CCE bowel preparation was prescribed initially (Table 1) [19]. For the booster agents, the Phospho Soda booster (CB Fleet Co. Inc., Lynchburg, Virginia, USA) was replaced with sodium picosulfate (Picolax; Ferring Pharmaceuticals Ltd., Dublin, Ireland) due to serious safety concerns and product availability. On the day of CCE (Day 1), participants consumed the second half of the split-dose bowel preparation. Participants were fitted with a digital recorder belt and asked to swallow the capsule (PillCam COLON 2; Given Imaging). Participants were monitored until the capsule passed the duodenum, as visualized on the recorder. At this point, a 250-mL bowel preparation booster was taken and participants were then allowed to leave the unit. Participants were prompted 3 hours later to take the second booster dose by an automated alarm on the recorder (Table 1). An hour after this, they were allowed to drink liquids. Participants returned to the unit the following morning to undergo standard optical colonoscopy, and the recorder belt was removed for analysis. The images were downloaded from the recorder and read using the Rapid reader 6.8 (Given Imaging). All CCEs were read by a consultant gastroenterologist with experience and training in CCE techniques. For each study report, the following items were recorded: bowel preparation quality, study completion (defined by visualization of the dentate line), and the location, size, and number of any polyps and cancers. Significant neoplasia was defined as more than three polyps in one individual or any polyp larger than 10 mm. The quality of bowel preparation was reported using a standard cleansing level evaluation form

Table 1 Bowel preparation schedule for colon capsule endoscopy using the PillCam COLON 2 capsule.

Day – 2	4 senna tablets 10 Glasses of water
Day – 1	Liquid diet 16:00 hours: 2 L of PEG
Day 1, time	
08:00	2 L PEG
08.45	Swallow capsule
Small bowel detected	1st booster
3 hours later	2nd booster
22:00	If capsule not passed, rectal bisacodyl suppository
Day 2	Optical colonoscopy

PEG, polyethylene glycol.

(not yet validated), which divides the colon into five sections (cecum, right colon, transverse colon, left colon, and rectum), and four cleansing grades (poor, fair, good, and excellent). However, for the purposes of evaluating the clinical efficacy of CCE, as with colonoscopy, the cleansing result was classified as either adequate or inadequate.

Optical colonoscopy procedure

The optical colonoscopy was performed on Day 2 under conscious sedation as per standard practice, by experienced and screening-approved colonoscopists who were blinded to the CCE results. The preparation quality, completion rates (defined by visualization of the cecum, confirmed by a photograph and/or intubation of the ileocecal valve), and location, size, and number of polyps and cancers were recorded. Any polyps detected were removed and sent for histological analysis. Significant neoplasia was defined as for CCE examinations, with the addition of a greater than 10% villous component on histology.

Complication rates were recorded immediately following each procedure and on follow-up 30 days after the procedure by telephone interview.

Statistical analysis

All analyses were performed using SPSS version 20 (IBM Corp., Armonk, New York, USA). Results were expressed as means. Completion rates, adenoma and cancer detection rates, and complications were compared between groups using a Student's *t* test or chi-squared test, as appropriate, and a *P* value of <0.05 was considered to be significant. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for CCE were calculated using optical colonoscopy results as the gold standard. Cohen's kappa was used to assess the correlation between CCE and optical colonoscopy findings.

Results

A total of 62 people with at least one positive FIT result agreed to undergo both CCE and optical colonoscopy procedures. The mean age was 62.5 ± 5.8 years (range 41–73 years), and there were 34 men (55%). All recruited participants underwent CCE first on Day 1, followed by optical colonoscopy on Day 2, as per the protocol. The Phospho Soda booster was used in the first 16 participants (26%), and subsequent participants received picosulfate boosters. A total of 96 polyps in 36 participants (58%) were detected on optical colonoscopy. In all, 29 participants had an adenoma, and cancer was diagnosed in one participant (2%). Other findings at optical colonoscopy included colitis in two participants (3%) and a solitary rectal ulcer in one participant (2%).

Capsule colonoscopy

All participants were able to swallow the colon capsule. The capsule was excreted or reached the dentate line within the recording time in 46 participants (73%). There was a significant difference in completion rates according to the type of booster employed in the procedure: 88% (14/16) in the Phospho Soda group and 70% (32/46) in the picosulfate group ($P < 0.05$). The mean time to reach the cecum was 2.56 hours (range 60–311 minutes), and for those in whom the capsule was excreted the mean time to excretion was 7 hours. CCE detected polyps (any type) in 43 participants (69%), significant neoplasia in 18 participants (29%), and cancer in one participant (2%) (● Fig. 1; ● Table 2).

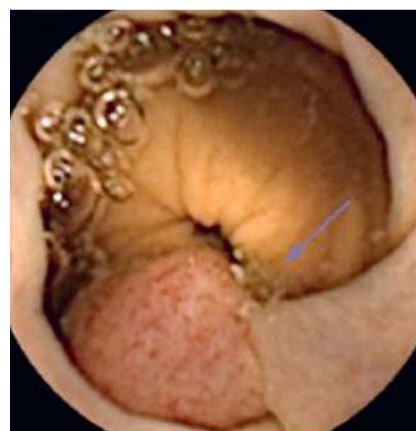


Fig. 1 Polyps visualized on colon capsule endoscopy

Table 2 Polyp and significant lesion detection on optical colonoscopy and colon capsule endoscopy.

	Any polyp	Significant lesion
CCE, n	43	18
Optical colonoscopy, n	36	18
Cohen's kappa	0.62	0.84
95%CI	0.42–0.81	0.695–0.991
Likelihood ratio	2.71	22.25

CCE, colon capsule endoscopy.

The quality of bowel preparation was reported to be adequate in 92% ($n = 57$). Five participants had poor or inadequate bowel preparation, two of whom (40%) had polyps detected, compared with 34/57 (60%) of those who had adequate bowel preparation, although this difference did not reach statistical significance. There were no early or late adverse events from the colon capsule.

Optical colonoscopy

The overall cecal intubation rate was 94% ($n = 58$). Of the incomplete procedures, the bowel preparation was poor in two participants (3%) and required a repeat procedure. For analysis of polyp detection rates, the repeat procedures were used for comparison with CCE findings. On optical colonoscopy, 36 participants (58%) had at least one polyp and one participant had a proximal rectal cancer (● Table 2). The cancer and adenoma detection rates confirmed by histology in this group were 2% ($n = 1$) and 45% ($n = 28$), respectively. The remaining participants had hyperplastic polyps ($n = 8$, 13%). Significant lesions were found in 18 participants (29%). One participant (2%) was admitted 24 hours after the procedure with a postpolypectomy bleed, which required a blood transfusion, repeat colonoscopy, and clipping of a visible vessel at the polypectomy base.

Optical colonoscopy and CCE concordance Cancer detection

Only one participant undergoing a screening colonoscopy was diagnosed with cancer (2%). This cancer detection rate is in keeping with the rate of 3% generally found at the second round of screening in our pilot population (unpublished data). The cancer was detected by both CCE and optical colonoscopy.

Polyp detection

The polyp detection rate for optical colonoscopy was 58 % (n = 36). Overall, the sensitivity, specificity, PPV, and NPV of CCE for any polyp compared with optical colonoscopy was 95 %, 65 %, 79 %, and 90 %, respectively, with nine false-positive and two false-negative CCEs (● Fig. 2; ● Table 2 and ● Table 3). A total of 18 participants had significant lesions on optical colonoscopy, and the sensitivity, specificity, PPV, and NPV of CCE for significant lesions was 89 %, 96 %, 89 %, 96 %, respectively, with two false-positive and two false-negative CCEs (● Table 4). Of note, both false-negative CCEs were due to more than three polyps being detected on optical colonoscopy. CCE did not miss any lesions that were larger than 10 mm or had high grade dysplasia on subsequent histology. The overall correlation between CCE and optical colonoscopy for any polyp and significant neoplasia was good and excellent with Cohen's kappa of 0.62 and 0.84, respectively.

Discussion

This study demonstrates that the second-generation PillCam COLON capsule is safe and effective in screening for colonic polyps and cancer in a FIT-positive cohort. In particular, if the capsules were to be used as a filter test, as we propose, they have shown excellent NPVs for any polyp and significant lesions, at 90 % and 96 %, respectively, and could reduce the demand for optical colonoscopy by up to one-third (● Fig. 3). In an average-risk population, Pilz et al. found a similar NPV of 93 % [20]. Although the overall polyp detection rate with CCE is high at 69 %, significant lesions were present in only 29 %, and this would appear to be a more suitable threshold for colonoscopy. Significant lesions on CCE had a PPV and NPV of 89 % and 96 %, respectively, and no cancers or lesions with high grade dysplasia were overlooked. If such a filter test strategy were to be employed, from the current cohort of 62 participants, 44 (71 %) would have safely avoided colonoscopy. In recent years, a similar strategy has been advocated for computed tomography (CT) colonography. In the US Preventive Services Task Force guidelines on screening, CT colonography specifically does not report on polyps that are smaller than 5 mm. This cutoff size was developed due to the unacceptable level of false-positive results for smaller polyps. Similarly, in the current study, CCE and optical colonoscopy had good concordance for significant lesions (r=0.84). Given the low likelihood of malignancy in smaller polyps, the use of significant lesions as a trigger for optical colonoscopy would appear to be both safe and effective. Some readers may feel that all participants with positive FIT results should undergo full optical colonoscopy, given the high rate of cancer in this group. However, in the current study, 53 % of participants had no neoplasia. This implies that a significant number of screening participants are being exposed unnecessarily to the risks of colonoscopy and sedation, in addition to occupying endoscopy beds and taking up staff resources. Furthermore, a large group of individuals in the screening age group would be more suitable for CCE than optical colonoscopy, such as those with significant co-morbidities and those on anticoagulants. Use of a filter test could therefore significantly reduce the overall adverse events for a screening program. Using optical colonoscopy as a gold standard may overestimate the false-negative rate for CCE, as it is well recognized that colonoscopy does not have 100 % sensitivity for polyps and that the



Fig. 2 False-positive polyp on colon capsule endoscopy.

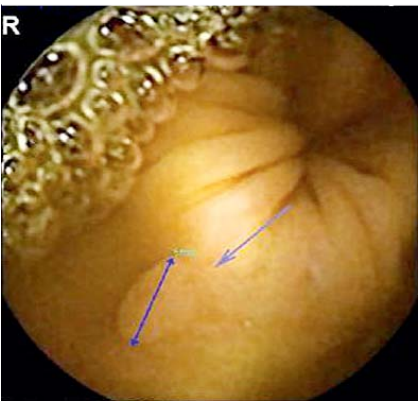


Fig. 3 Expected outcome based on colon capsule endoscopy (CCE) as a filter test in a fecal immunological test (FIT)-based screening program.

Table 3 Colon capsule endoscopy findings compared with optical colonoscopy results for all polyps.

	Colonoscopy positive	Colonoscopy negative	
CCE positive	34	9	PPV 79 %
CCE negative	2	17	NPV 90 %
Sensitivity 95 %		Specificity 65 %	

CCE, colon capsule endoscopy; NPV, negative predictive value; PPV, positive predictive value.

Table 4 Colon capsule endoscopy findings compared with optical colonoscopy results for significant lesions.

	Colonoscopy positive	Colonoscopy negative	
CCE positive	16	2	PPV 89 %
CCE negative	2	42	NPV 96 %
Sensitivity 89 %		Specificity 96 %	

CCE, colon capsule endoscopy; NPV, negative predictive value; PPV, positive predictive value.

sensitivity varies depending on a number of factors. It could be argued that the nine polyps on CCE that were not confirmed by optical colonoscopy are not in fact false-positive results but polyps missed on colonoscopy (● Fig. 2). However, it was beyond the scope of this study to repeat the optical colonoscopy, which would be the best way to assess these false-positive results. In addition, as this was an early study of the use of CCE in screening, it

was important to evaluate the NPV of CCE. In order to avoid bias, a blinded study design was adopted. In a study to assess the accuracy of CCE, an unblinded optical colonoscopy would be the preferred option, and future studies with this design would be welcome.

Participation rate is one of the most important key performance indicators in any population-based screening program. Despite colonoscopy being the most accurate screening test for CRC, it is often perceived as painful and dangerous, and uptake is reported to be very low, at below 5%. Having the option of a CCE may help to increase participation rates. Groth et al. demonstrated that the option of CCE resulted in a fourfold increase in screening uptake, particularly in men [21].

In the current study, participants were randomly selected from within a screening pilot from those with a positive FIT result who were willing to undergo both tests. In future, however, if CCE was adopted as a filter test, it may be possible to use the FIT results to further pre-select participants with a lower likelihood of polyps on optical colonoscopy, and therefore further reduce the number of unnecessary colonoscopies. Younger participants (50–59 years), and in particular women, are less likely to have neoplasia and so could be selected to undergo CCE first as a filter test rather than being referred straight away for full optical colonoscopy. Alternatively, a pre-specified FIT cutoff could be used, as studies have indicated that the higher the FIT level the higher the risk of neoplasia [22].

The overall incomplete study rate for CCE in the current group was quite high (27%), and this needs to be addressed. This is likely to be due to the use of sodium picosulfate as a booster in the majority of studies. The completion rate with Phospho Soda boosters was higher at 88%. There are ongoing advances in colon capsule preparation, and several current studies are under way to determine the optimal preparation [23–25]. It is likely that improvements in bowel preparation will further enhance the clinical efficacy CCE. However, all incomplete examinations in the current study reached at least the sigmoid colon at 10 hours. Therefore, an incomplete capsule examination would probably only require a sigmoidoscopy to complete the study. In the incomplete cohort, the NPV remained high at 100%, and all participants with polyps on optical colonoscopy were detected.

The study does have some limitations: the relatively small number of participants and the acknowledged low completion rate of CCE. However, to our knowledge, this is the first study to use CCE in a FIT-positive population-based screening cohort, and the largest single-center screening CCE study to date. The screening center has established experience with PillCam colonoscopy, and adopts a standardized approach to CCE procedures and reporting; this reduces the likelihood of interobserver variability, which is found in some multicenter studies.

Despite these limitations, the study has confirmed the clinical efficacy of CCE and supports its role within CRC screening. Additional larger studies are required to determine the potential role of CCE as a filter test in this setting.

Conclusion

This study demonstrated that CCE is a safe and effective tool for the detection of colorectal polyps and cancer in a FIT-positive screening cohort. Based on the high NPV, particularly for significant lesions, CCE could be a suitable filter test to use for selection of screening participants for subsequent optical colonoscopy. CCE has the potential to significantly reduce the number of unneces-

sary negative screening procedures, while enhancing the yield of subsequent colonoscopies in the positive CCE cohort.

Competing interests: The PillCam COLON 2 capsules used in this study were supplied free of charge by Given Imaging Ltd.

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