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Colon capsule endoscopy following incomplete colonoscopy in routine clinical settings

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Abstract

Background Colon capsule endoscopy (CCE) was introduced in our department on two indications; following incomplete colonoscopy as an alternative to CT colonography, and in patients with a history of incomplete colonoscopy as an alternative to anesthesia-assisted (AA) colonoscopy. We aimed to compare the quality of CCE, defined by completion rate and polyp detection rate (PDR), with that of CT colonography and AA colonoscopy, respectively.

Methods Patients referred for CCE from May 2020 until November 2021 were consecutively included in this prospective cohort study. Demographics, indication and CCE outcomes were registered from the electronic patient record. Completion rate and PDR in CCE as an alternative to CT colonography were compared with those of a historical cohort undergoing CT colonography following incomplete colonoscopy. Completion rate and PDR in CCE as an alternative to AA colonoscopy were compared with those of a time true parallel cohort undergoing AA colonoscopy.

Results In 65 patients undergoing CCE, 36 (57%) were referred as an alternative to CT colonography. The completion rate in this group was 44% compared to 96% in CT colonography ($p < 0.001$). The PDR in complete CCE in this group was 75% in CCE compared to 20% in CT colonography ($p < 0.001$). The remaining 27 (43%) of the sample were referred for CCE as an alternative to AA colonoscopy. The completion rate in this group was 33% compared to 100% in AA colonoscopy ($p < 0.001$). The PDR in complete CCE in this group was 78% in CCE compared to 35% in AA colonoscopy ($p = 0.013$).

Conclusions The completion rate of CCE following incomplete colonoscopy is inferior to that of CT colonography and AA colonoscopy. The PDR of CCE was high, indicating an acceptable sensitivity in complete investigations, but in our settings the completion rate of CCE on this indication is unacceptably low.

Clinical trial registration: NCT04307901 (ClinicalTrials.gov, March 13, 2020).

Keywords Colon capsule endoscopy · Incomplete colonoscopy · Completion rate · CCE · Colonoscopy · CT colonography

Colonoscopy is a commonly performed procedure with millions performed yearly in Europe and the volume is increasing [1]. 4–25% of colonoscopies are incomplete, often due to patient discomfort [2–5]. The investigation following incomplete colonoscopy varies between hospitals, but according to European guidelines the primary recommended investigation after incomplete colonoscopy is CT colonography (strong recommendation), or alternatively colon capsule endoscopy (CCE) (weak recommendation) [6]. The implementation of CCE in clinical settings is still limited. Earlier studies have reported successful use of CCE following an incomplete colonoscopy [7–9], which can reduce the risk of complications, and the costs of anesthesia when compared to anesthesia-assisted (AA) re-colonoscopy.

CT colonography is a reliable method for detecting larger polyps, but CCE is more sensitive to smaller polyps and flat lesions [7, 8, 10]. De Haan et al concludes that CT colonography, compared to colonoscopy, is an acceptable method for detection of polyps ≥ 10 mm in a symptomatic population [10]. Spada et al. compared CT colonography and CCE in patients with previous incomplete colonoscopy and found a significantly higher sensitivity for polyps ≥ 6 mm by CCE. In the same study, CCE detected twice the number of

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polyps ≥ 6 mm as compared to CT colonography [7]. Deding et al. backs this conclusion by demonstrating that the relative sensitivity of CCE was 2.7 compared to CT colonography for polyps larger than 5 mm in patients with previous incomplete colonoscopy [8]. With this empirical evidence in mind and the ESGE guidelines on the matter, it seemed sound to introduce CCE following incomplete colonoscopy to our clinical practice in an all-comers population. To evaluate the implementation of CCE and the performance in routine clinical diagnostics, we aimed to compare the quality of CCE, defined by completion rate and polyp detection rate (PDR), with that of CT colonography and AA colonoscopy. In this report, we define CCE completion rate as the rate of investigations with both complete transit during battery lifetime and acceptable bowel cleanliness.

Materials and methods

Patients and setting

In May 2020, the Department of Surgery at Odense University Hospital introduced CCE as a routine diagnostic modality on two indications;

I. Following incomplete colonoscopy as an alternative to CT colonography.
II. In-house patients with a history of incomplete colonoscopy as an alternative to anesthesia-assisted colonoscopy.

Individuals referred for CCE were prospectively included in our study and entered into our database upon their signed consent for participation. Individuals not signing the consent form were offered the same diagnostic pathway. Patients with poor bowel preparation at incomplete colonoscopy, stenosis, previous colonic resection, ostomy, inflammatory bowel disease, dysphagia, dysregulated diabetes, kidney dysfunction, pacemaker, pregnancy or waist measure > 140 cm were not eligible for CCE as defined by department guidelines.

All CCE investigations were performed using the second-generation PillCam2 (Medtronic, Minneapolis, MN, US). Bowel preparation regimen was a split-dose polyethylene glycol solution (2 L) prior to capsule ingestion and a split-dose sodium picosulfate (1 L) as boosters after ingestion. A detailed bowel cleansing regime is provided in appendix A. Inclusion ended in December 2021. Patients underwent bowel preparation at home and reported for capsule ingestion in the morning at an outpatient facility. After ingestion, patients went home but were in continuous contact with clinical staff guiding them through the procedure until excretion of the capsule. The video was subsequently reviewed by experienced readers by Corporate Health International (Hamburg, Germany).

Reference cohorts

In order to evaluate the quality of CCE investigations, we compared the outcomes with those of the standard investigation modality in the hospital for each indication.

Following incomplete colonoscopy, the standard referral would be to CT colonography. Previously, we conducted a trial in which patients from our department were referred to CT colonography following incomplete colonoscopy [8]. CT colonography was performed with a Siemens Somatom Definition Edge 64-slice CT scanner and results evaluated by certified abdominal radiologists. We compared the CCE outcomes with the CT colonography outcomes of the historical cohort from this trial. For patients with a history of incomplete colonoscopy, the standard referral would be for AA colonoscopy. AA colonoscopy is defined as under general anesthesia or under propofol sedation with patient characteristic dependent dosage as per discretion of the anesthetist. The colonoscopy standard of practice at the department is sedation with an anxiolytic (Midazolam) and an opioid agonist (pethidine) intravenously 2 and 20 mg, respectively, (dosage can vary from 2 to 5 and 20 to 50 mg, respectively, at the discretion of the endoscopist). We drew a random sample of 300 patients undergoing AA colonoscopy in our department during the same period as our CCE cohort underwent CCE. The randomization was conducted using the surveyselect function in SAS software version 9.4 (SAS Institute Inc., SAS 9.4., Cary, NC, USA). Outcome data from this group were retrieved through the electronic patient file and compared to the CCE outcomes. Eligibility criteria for CT colonography and AA colonoscopy were matched to those of the CCE cohort.

Investigation quality

The quality of an investigation was determined by the completion rate and the PDR. PDR was defined as the proportion of patients with ≥ 1 polyp out of all complete investigations, and in all examinations regardless of completion, respectively. The term polyp includes hyperplastic and other non-neoplastic lesions, adenomas, and tumors. Additionally, the PDR calculation was limited to polyps greater than 5 and 9 mm, respectively. A complete CCE investigation was defined by at least a fair level (Leighton Rex scale) of bowel preparation in each colonic segment (caecum, right colon, transverse colon, left colon, rectum), combined with a visual of the anal valve (complete transit). A complete CT colonography was defined by a total visualization of the colon and rectum with sufficient bowel distention, no persistent strictures, and an acceptable bowel preparation. A complete

AA colonoscopy was defined as complete by a visualization of the caecal valve and/or terminal ileum, and an acceptable bowel preparation at the discretion of the endoscopist. Re-investigation rate was calculated as the proportion of patients needing further investigations after CCE.

Statistics

Baseline characteristics and investigation quality were compared using Wilcoxon signed rank test for continuous variables, and χ^2 test for categorical variables. In case of observations lower than five, the Fisher Exact test replaced the χ^2 test. Data management and statistical analyses were performed using SAS software version 9, 4 (SAS Institute Inc. SAS 9.4. Cary, North Carolina, USA).

Ethics

As the current study was based on observations of the present clinical practice, no approval from the regional health ethics committee was necessary (Ref. 20202000-12 Regional Health Research Ethics Committee). It was reported to the Regional Archive of Southern Denmark (Ref. 20/4408) for reasons of sensitive personal information and CCE patients signed consent forms allowing us to access their patient medical record. The sampling of data for the AA colonoscopy comparison was reported to the Regional Archive of Southern Denmark as an appendix to our study (Ref. 20/4408), and the transfer of the journal file data was reported to the Regional Secretariat (Ref. 21/21221). Patients undergoing CT colonography signed consent forms before inclusion in the previous clinical trial. Every patient was informed that they could withdraw consent at any time without consequences for their further treatment. The previous clinical trial on CT colonography was approved by the regional health research ethics committee (S-20150140), and by the Danish Data Protection Agency (16/16125) [8].

Results

Eighty-five patients underwent CCE from May 2020 until December 2021. Twenty individuals did not sign the consent form and two were excluded due to poor bowel preparation at incomplete colonoscopy. This left 63 CCE procedures for analyses of which 36 were referred as an alternative to CT colonography, and 27 were referred as an alternative to AA colonoscopy. The reasons for incomplete colonoscopy in the 36 referred as an alternative to CT colonography were reported as pain ($n=21$) or lack of advancement ($n=15$). In the reference cohort sample of 300 AA colonoscopy patients, 190 met did not meet eligibility criteria leaving 110 for analysis. Reasons for previous incomplete colonoscopy were not known in this group. In the historical cohort, 105 patients were referred for CT colonography of which six dropped out (Fig. 1). Reasons for incomplete colonoscopy in these 99 patients were looping ($n=23$), pain ($n=39$), redundant colon ($n=6$), severe angulations ($n=22$), stenosis ($n=4$), suspected adhesions (3), and not specified in the remaining two.

No significant differences in gender or age composition were seen between the groups, but indication for primary

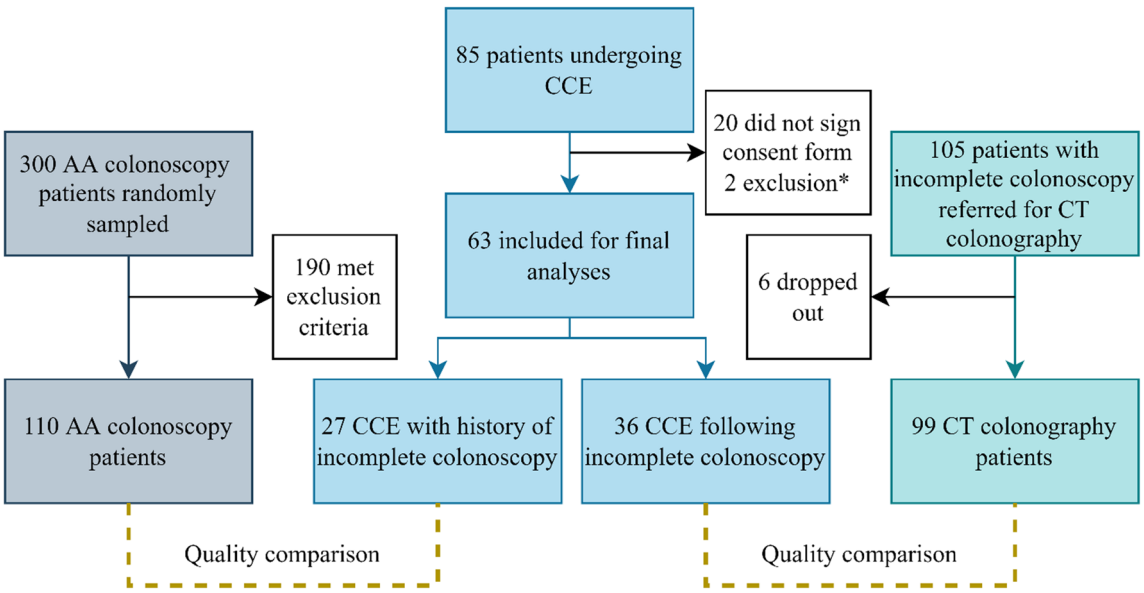

Fig. 1 Flow chart of AA colonoscopy, colon capsule endoscopy, and CT colonography cohorts for comparisons. *Poor bowel preparation at incomplete colonoscopy. *AA* Anesthesia-Assisted, *CCE* Colon Capsule Endoscopy, *CT* colonography Computed Tomography Colonography

colonoscopy differed between CCE and comparison groups (Table 1). For the entire CCE sample, the completion rate of CCE was 40%, the complete transit rate was 60% and the bowel preparation was acceptable in 54%. In complete CCE investigations, a mean number of 2.1 polyps were identified per patient and the PDR was 76%, 56%, and 20% for polyps any size, over 5 mm and over 9 mm, respectively. No complications occurred associated with the CCE investigations.

In 63 CCE patients, 48 (76%) needed further investigations (Table 2), of which 21 was solely due to incomplete examination, 10 was solely due to findings and 17 was due to both. Of the four individuals referred to CT colonography, two had polyp findings at CCE (7 mm or smaller) but no polyp findings at CT colonography. Of the 44 individuals referred to colonoscopy, 37 had polyps findings at CCE (20 mm or smaller) of who 24 had polyp findings at the following colonoscopy. One in seven individuals referred to colonoscopy with no polyps findings at CCE had a polyp (2 mm) found at the following colonoscopy.

Table 2 Colon capsule endoscopy performance

All CCE investigations	CCE, $n=63$
Complete investigations	25 (40%)
Complete transit	38 (60%)
Acceptable bowel preparation	34 (54%)
Mean polyp count	2.2
Mean polyp count in complete investigations	2.1
Polyp detection rate	
Any size	51 (81%)
Polyp detection rate, > 5 mm	35 (56%)
Polyp detection rate, > 9 mm	13 (21%)
Polyp detection rate in complete examinations ($n=25$)	
Any size	19 (76%)
> 5 mm	14 (56%)
> 9 mm	5 (20%)
Re-investigation rate	48 (76%)
AA colonoscopy	44 (70%)
CT colonography	4 (6%)

AA Anesthesia-Assisted, *CCE* Colon Capsule Endoscopy, *CT* colonography Computed Tomography Colonography

Quality comparisons

The completion rate of CCE as an alternative to CT colonography was 44% (complete transit in 67%) compared to 96% in CT colonography ($p<0.001$). Acceptable bowel preparation was achieved in 56% of CCE compared to 96% in CT colonography ($p<0.001$). In complete CCE investigations, the mean polyp count was 2.4 compared to 0.3 in CT colonography ($p<0.001$). In complete CCE investigations, the PDR was 75%, 56%, and 25%, compared to 20%, 18%, and 13% in CT colonography for polyps any size ($p<0.001$), polyps over 5 mm ($p=0.002$), and polyps over 9 mm ($p=0.122$), respectively (Table 3).

The completion rate of CCE as an alternative to AA colonoscopy was 33% (complete transit in 52%) compared to 100% in AA colonoscopy ($p<0.001$). Acceptable bowel preparation was achieved in 52% of CCE compared to 100% in AA colonoscopy ($p<0.001$). In complete CCE investigations the mean polyp count was 1.6 compared to 0.6 in AA colonoscopy ($p=0.008$). In complete CCE investigations,

Table 1 Baseline characteristics stratified by indication

Indication: alternative to CT colonography	CCE, $n=36$ (%)	CT colonography, n = 99 (%)	*P*-value
Females	30 (83.3)	73 (73.7)	0.246
Age, mean (IQR)	63 (53–72)	62 (53–71)	0.682
Indication primary colonoscopy (incomplete)			
Symptoms	32 (88.9)	50 (50.5)	
Surveillance	4 (11.1)	6 (6.1)	
Screening	0 (0.0)	41 (41.4)	< 0.001
Missing	0 (0.0)	2 (2.0)	
Indication: alternative to AA colonoscopy	CCE, $n=27$ (%)	AA colonoscopy, n = 110 (%)	*P*-value
Females	17 (63.0)	82 (74.5)	0.228
Age, mean (IQR)	60 (55–70)	59 (50–70)	0.425
Indication primary colonoscopy (incomplete)			
Symptoms	20 (74.1)	53 (48.2)	
Surveillance	5 (18.5)	31 (28.2)	
Screening	2 (7.4)	26 (23.6)	< 0.001

AA Anesthesia-Assisted, *CCE* Colon Capsule Endoscopy, *CT* colonography Computed Tomography Colonography, *IQR* Inter Quartile Range

Table 3 Investigation outcomes stratified by indication

Indication: alternative to CT colonography	CCE, $n=36$ (%)	CT colonography, $n=99$ (%)	P-value
Complete investigations	16 (44%)	95 (96%)	< 0.001
Complete transit	24 (67%)	–	
Acceptable bowel preparation	20 (56%)	95 (96%)	< 0.001
Mean polyp count	2.4	0.3	< 0.001
Mean polyp count in complete investigations (n = 16/95)	2.4	0.3	< 0.001
Polyp detection rate			
Any size	30 (83%)	19 (19%)	< 0.001
> 5 mm	21 (58%)	17 (17%)	< 0.001
> 9 mm	8 (22%)	12 (12%)	0.144
Polyp detection rate in complete investigations ($n=16/95$)			
Any size	12 (75%)	19 (20%)	< 0.001
> 5 mm	9 (56%)	17 (18%)	0.002
> 9 mm	4 (25%)	12 (13%)	0.122
Indication: alternative to AA colonoscopy	CCE, $n=27$ (%)	AA colonoscopy, $n=110$ (%)	P-value
Complete investigations	9 (33%)	110 (100%)	< 0.001
Complete transit	14 (52%)	–	
Acceptable bowel preparation	14 (52%)	110 (100%)	< 0.001
Mean polyp count	2.0	0.6	< 0.001
Mean polyp count in complete investigations (n = 9/110)	1.6	0.6	0.008
Polyp detection rate			
Any size	21 (78%)	38 (35%)	< 0.001
> 5 mm	14 (52%)	24 (22%)	0.002
> 9 mm	5 (19%)	17 (15%)	0.698
Polyp detection rate in complete investigations ($n=9/110$)			
Any size	7 (78%)	38 (35%)	0.013
> 5 mm	5 (56%)	24 (22%)	0.031
> 9 mm	1 (11%)	17 (15%)	0.376

AA Anesthesia-Assisted, *CCE* Colon Capsule Endoscopy, *CT* colonography Computed Tomography Colonography

the PDR was 78%, 56%, and 11%, compared to 35%, 22%, and 15% in AA colonoscopy for polyps any size ($p=0.013$), polyps over 5 mm ($p=0.031$), and polyps over 9 mm ($p=0.376$), respectively (Table 3).

Discussion

In the current study implementing CCE in routine clinical practice, we found a completion rate of CCE, which was clearly inferior compared to CT colonography and AA colonoscopy in patients with incomplete colonoscopy. Complete investigation rates of 44% and 33% is unacceptable. The ESGE guideline [6] recommends CCE in patients with incomplete colonoscopy, but in our setting, CCE did not perform at a sufficient level. The PDR was significantly higher in CCE for polyps any size and polyp greater than 5 mm. This was the case for complete examinations as well as for all performed CCE. It is likely that the high PDR is indicating a higher ADR and that the CCE might become an attractive method if the high rate of incomplete investigations can be overcome. The completion rates were much lower than those previously reported [8, 11–16]. A systematic review ranged the completion rate of CCE at 65–93% and 75–98% in CT colonography in patients with incomplete colonoscopy [9]. The reason for the low completion rate in this study is unknown and we expected it to match previous findings. The low completion rate may be caused by selection bias since the referral to CCE was conducted as part of routine clinical practice, and therefore not blinded nor randomized. Selection bias is indicated as well by the difference in baseline characteristics between groups. The CCE group consists mainly of symptomatic patients, whereas the comparison groups consists of symptomatic patients, patients for surveillance, and CRC screening participants. The systematic review included all indications with no studies experiencing a completion rate nearly as low [9]. However, it seems unlikely that

the composition of population is the reason for the low completion rate. The lower completion rate may simply be because we introduced CCE in actual clinical practice for an all-comers population, demonstrating real life value of CCE on this indication rather than testing it in a prospective trial. The incomplete CCE examinations were equally caused by poor bowel preparation and incomplete transit. Therefore, improving the bowel preparation by enhancing or altering the regime is probably not enough to solve the issue by itself. Boosters or other activities increasing peristalsis may additionally be needed in order to speed up the progression of the capsule. We have demonstrated prucalopride to able to improve both parameters in a screening population [17], although a starting point of 40% completion rate seem to love for a simple fix solution.

Previous studies comparing CCE and CT colonography in patients with previous incomplete colonoscopy found a higher polyp sensitivity in CCE compared to CT colonography [7, 8]. A meta-analysis comparing CT colonography and colonoscopy found the specificity of CT colonography for adenomas ≥ 10 mm good at 97.6%, but for smaller adenomas ≥ 6 mm the specificity was lower at 91.4 [10]. Our results support the findings of these studies as the CCE group has the highest PDR for polyps any size, > 5 and > 9 mm. The CCE group has the highest mean number of polyps per investigation (in complete as well as incomplete investigations) indicating a superiority in polyp detection even with the low completion rate. The PDR was significantly higher in CCE, but not when limiting the analysis to polyps greater than 9 mm. The increased PDR and mean number of polyps in CCE may be caused by CT colonography and colonoscopy missing the smaller polyps more often than CCE. On the other hand, it may be attributable to double reporting of polyps in CCE [18]. Double reporting of polyps can cause an overestimation of the risk assessment, causing the patient to undergo unnecessary additional bowel preparation and investigations. As the capsule can progress both forward and backwards in the colon, the same polyp may be seen more than once with a substantial number of frames in between, rendering the task of determining whether a polyp has been seen before very troublesome.

In our setting, the 60% risk of incomplete CCE and 76% risk of re-investigation, leading to additional bowel cleansing and follow-up procedures outweighs the benefit of an increased PDR, hence CCE is not a viable modality. If the completion rate can be increased to similar rates as seen elsewhere, the polyp sensitivity may outweigh the drawback of the completion rate. On the basis of our data and experience, we have not found CCE clinically applicable in this specific patient group and investigational indications. Thus, this modality is no longer incorporated in our diagnostic strategy towards patients with incomplete colonoscopy.

Conclusions

In our setting, the completion rate of CCE following incomplete colonoscopy is inferior to that of CT colonography and AA colonoscopy. The PDR of CCE was high, but in order for CCE to be a viable investigation modality for patients with incomplete colonoscopy, the completion rate must be increased.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-022-09783-w.

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Declarations

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