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# **Adherence to the bowel cleansing regimen for pan-enteric capsule endoscopy in patients with suspected Crohn's disease and factors affecting the image quality**

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## **Abstract** (250 words)

**Objective:** Pan-enteric capsule endoscopy (CE) is an attractive diagnostic approach in patients examined for Crohn's disease (CD). The aim of this study was to examine the adherence to the recommended bowel cleansing regimen and determine clinical factors affecting the image quality.

**Methods:** In a prospective blinded trial, patients with suspected CD were examined with the PillCam Crohn's capsule after bowel preparation with 2+2 litres of Polyethylene glycol (PEG) and Sodium Phosphate booster. The image quality was graded on a 4-point scale. A good or excellent image quality defined a diagnostic procedure.

**Results:** 59 patients participated. The mean volume of PEG was 2.5 L (CI 2.3-2.8). 10 patients (17%) were able to drink all 4 L of PEG, and 44 patients (75%) ingested  $\geq 2$  L. The image quality was poor, fair, good or excellent in 0%, 29.3%, 29.3% and 41.4%, respectively. The mean volume of PEG was 1.9 L (CI 1.4-2.4), 2.2 L (CI 1.8-2.7) and 3.2 L (CI 2.8-3.5) in patients with a fair, good or excellent image quality ( $P < 0,001$ ). In a regression analysis, only the volume of PEG was associated with the obtained image quality ( $r_s = 0.52$ ;  $P < 0.001$ ). The diagnostic yield was equal in patients with a diagnostic or non-diagnostic procedure (43.9% and 47.1%, respectively).

**Conclusions:** In patients examined with pan-enteric CE for suspected CD, the volume of PEG is the major factor affecting the image quality. Although few patients are able to ingest the recommended volume, the diagnostic yield is not affected.

**Keywords:** Crohn's disease, capsule endoscopy, bowel cleansing

## **Introduction**

Ileocolonoscopy with segmental biopsies is the preferred modality for the initial diagnosis of Crohn's disease (CD) [1]. However, the examination is invasive, associated with patient discomfort and a small risk of colonic perforation (< 1 per 1,000 colonoscopies) [2]. Conscious sedation is often required [3], and a complete ileocolonoscopy is not always possible.

Since its FDA approval in 2001, capsule endoscopy (CE) has revolutionized gastrointestinal imaging. CE is highly sensitive, patient friendly, less invasive and compared to cross sectional imaging, CE allows a direct and detailed evaluation of the gastrointestinal mucosa with detection of the earliest lesions of CD [1, 4]. Pan-enteric CE is now available allowing a detailed evaluation of the entire gastrointestinal tract in one procedure. There are drawbacks with pan-enteric CE, however. Biopsies for histological verification is not possible, there is a risk of capsule retention in patients with stricturing CD, a complete coverage of the gastrointestinal tract is not always achieved and the technical inability to wash away or aspirate the contents of the colon requires extensive bowel preparation for a good visualization of the mucosa. The current bowel cleansing regimen was developed for colon CE in patients with suspected gastrointestinal neoplasia. Since the majority of patients with CD have diarrhoea, a reduced volume of bowel preparation may be sufficient for cleansing the colon, and a targeted regimen for this group of patients is warranted.

The aim of this study was to examine the adherence to the recommended bowel cleansing regimen in patients with suspected CD examined with pan-enteric CE and determine clinical factors affecting the image quality.

## **Methods**

Patients with suspected CD were recruited from three centres in the Region of Southern Denmark managing adult patients with inflammatory bowel diseases. All patients were prospectively enrolled in a clinical trial examining non-invasive modalities for diagnosing suspected CD (<http://ClinicalTrials.gov> Identifier NCT03134586). Participants who recorded the volume of polyethylene glycol (PEG) ingested before pan-enteric CE were included in this analysis.

CD was clinically suspected in patients with diarrhoea and/or abdominal pain for more than 1 month (or repeated episodes of diarrhoea and/or abdominal pain) associated with a faecal calprotectin > 50 mg/kg and at least one additional finding suggesting CD: elevated inflammatory markers,

anaemia, fever, weight loss, perianal abscess/fistula, a family history of inflammatory bowel disease, or suspicion of CD after sigmoidoscopy. Use of NSAID's was an exclusion criterion. All patients had a standardized work-up including medical history, physical examination, blood and stool samples, ileocolonoscopy, pan-enteric CE, magnetic resonance imaging enterocolonography, and bowel ultrasound.

### *Capsule endoscopy regimen*

Pan-enteric CE was performed with the PillCam™ Crohn's capsule (Medtronic, Dublin, Ireland) after the following bowel preparation previously described by ESGE [5]:

Two days before CE:	10 mg Bisacodyl orally at bedtime.
The day before CE:	Clear liquid diet throughout the day. 2 L of PEG ingested in the evening.
The day of CE:	2 L of PEG ingested before attending the gastroenterology outpatient clinic. 1 <sup>st</sup> boost: 30 ml of Sodium Phosphate solution. 2 <sup>nd</sup> boost: 25ml of Sodium Phosphate solution. 10 mg Bisacodyl suppository 2 hours after 2 <sup>nd</sup> boost.

Patients recorded the volume of PEG. The amount of booster ingested during the procedure was not registered. Images were reviewed with the PillCam™ software v9, and findings were reported in a standardized fashion according to the Capsule Endoscopy Standard Terminology (CEST) [6]. A complete small bowel evaluation was defined by capsule passage to the colon. A capsule expelled from the rectum defined a complete pan-enteric CE.

### *Colon cleansing*

The colon cleansing was graded on a 4-point scale [7]: *Poor*: Large amount of faecal residue precludes a complete examination. *Fair*: Enough faeces or turbid fluid to prevent a reliable examination. *Good*: Small amount of faeces or turbid fluid not interfering with examination. *Excellent*: No more than small bits of adherent faeces. A good or excellent image quality defined a diagnostic procedure.

### *Diagnostic criterion*

CD was diagnosed with CE by the presence of more than 3 aphthous ulcerations, irregular ulcers / fissures, or luminal narrowing caused by fibrosis or inflammation.

### *Clinical information*

Clinical data were collected during an interview performed 1 week prior to the CE procedure. The following data were recorded: Gender, age, height, weight, smoking, use of opioids or antidiarrheal drugs, use of NSAID's, stool frequency and stool consistency (hard, normal, alternating or watery).

### *Biochemistry*

Faecal calprotectin was measured prior to inclusion in the study as a part of the inclusion criteria. A repeat stool sample was not performed immediately prior to the CE procedure. C-reactive protein was measured 1 week before CE.

### *Statistics*

Continuous data were summarized using descriptive statistics. Kruskal-Wallis rank test was used to compare volumes of PEG in patient subgroups. Differences in diagnostic yields were tested for significance with a logistic regression model. The association between clinical variables and the degree of bowel cleansing was examined in a multiple linear regression model. Correlation was assessed with Spearman's rank correlation coefficient ( $r_s$ ).

### *Ethics*

The study was approved by the Local Ethics Committee of Southern Denmark (S-20150189) and the Danish Data Protection Agency (journal number 16/10457). All patients gave informed consent before participation.

### *Role of funding sources*

The study was initiated, planned and undertaken by the investigators without funding from pharmaceutical companies or the capsule endoscope manufacturer.

## Results

Fifty-nine patients were included in the study. Patient characteristics are shown in Table 1. The CE procedure was complete in 53 patients (89.8%). The capsule did not reach the colon in 2 patients and was not expelled from the rectum in 4 patients. One patient with a retained Crohn's capsule in the stomach was excluded from the analysis of image quality.

### *Volume of polyethylene glycol*

The mean total volume of ingested PEG was 2.5 L (CI 2.3-2.8) (Figure 1). A total of 4 (6.8%), 11 (18.6%), 18 (30.5%), 16 (27.1%) and 10 (17%) patients were able to drink < 1, 1-1.9, 2-2.9, 3-3.9 or all 4 L of PEG, respectively. The mean evening dose was higher than the morning dose, 1.4 L (CI 1.3-1.6) and 1.1 L (CI 0.9-1.3), respectively ( $P = 0.02$ ).

### *Image quality*

The CE image quality was rated poor, fair, good or excellent in 0 (0%), 17 (29.3%), 17 (29.3%) and 24 (41.4%) patients, respectively. The mean volume of PEG was 1.9 L (CI 1.4-2.4), 2.2 L (CI 1.8-2.7) and 3.2 L (CI 2.8-3.5) in patients with a fair, good or excellent image quality ( $P < 0.001$ , Figure 2). In a regression analysis including multiple clinical variables, only the volume of ingested PEG was associated with the obtained image quality (Table 2). There was a linear correlation between the ingested volume of PEG and the image quality with pan-enteric CE ( $r_s = 0.52$ ;  $P < 0.001$ ). The stool consistency and number of bowel movements prior to pan-enteric CE, diagnosis of inflammatory bowel disease, or the degree of inflammation determined by C-reactive protein and faecal calprotectin did not affect the obtained image quality.

### *Diagnostic yield*

Pan-enteric CE diagnosed inflammatory bowel disease in 26 of 58 patients (44.8%). Twenty (34.5%) patients had CD located in the small bowel (6), colon (5) or small bowel and colon (9). Although patients were included with suspected CD, 6 (10.3%) patients were diagnosed with ulcerative colitis (extensive colitis 5, left sided colitis 1). The mean volume of PEG was equal in patients with or without inflammatory bowel disease detected with pan-enteric CE, 2.5 L (CI 2.09-2.94) and 2.5 L (CI 2.17-2.92), respectively.

The diagnostic yield of pan-enteric CE was equal in patients with a diagnostic or non-diagnostic image quality (43.9% versus 47.1%,  $P = 0.83$ ). Forty-one CEs with a diagnostic image quality detected 13 patients with CD and 5 patients with ulcerative colitis compared to 7 patients with CD and 1 patient with ulcerative colitis detected with 17 non-diagnostic procedures.

#### *Completion rate*

Pan-enteric CE was incomplete in 6 (10.2%) patients, and the analysis did not have sufficient power to determine clinical or biochemical factors affecting the completion rate.

#### **Discussion**

This study included patients from gastroenterology outpatient clinics with suspected CD based on the clinical presentation and biochemical markers of inflammation thereby representing the diagnostic work-up in everyday clinical practice. Ileocolonoscopy with biopsies is the accepted gold standard and preferred modality for diagnosing ileocolonic CD, and CE is currently used as a second line procedure [1]. CE is patient-friendly, minimally invasive and, compared to cross-sectional imaging, highly sensitive for the earliest lesions of CD [4, 8]. Additional information obtained with CE about the proximal distribution of CD affects the prognosis and medical treatment [9-11]. Hence, CE is the preferred method for examining the small intestine in patients with suspected CD without obstructive symptoms [1, 12].

With the Crohn's capsule, pan-enteric evaluation in one procedure is now feasible [13-16]. Although the role of pan-enteric CE in CD is not yet established, it could play a major role in a future algorithm for non-invasive diagnosis and monitoring of CD. However, the extensive bowel preparation required to achieve a sufficient image quality is a major limitation.

Bowel cleansing has three main purposes: 1) cleaning the colon, 2) capsule propulsion, and 3) act as a medium for visualization of the mucosa. Preliminary studies using the same preparation as colonoscopy showed low excretion rates [17, 18]. Hence, a protocol combining 4 L of PEG and a booster preparation was adopted. It should be emphasized that the current bowel cleansing regimen was developed mainly for colon CE and patients examined for gastrointestinal neoplasia (polyps). There are no randomized controlled studies on the optimal bowel preparation in patients examined for CD with pan-enteric CE.



In clinical practice, the patient experienced discomfort is significant and a limiting factor for performing pan-enteric CE. In a study of the patient experienced discomfort, colon CE was associated with significant more discomfort (nausea, vomiting) compared to small bowel CE performed without bowel cleansing [19]. In patients examined for CD, the discomfort may be aggravated by concurrent bowel symptoms and gastrointestinal inflammation compared to other patient groups. Still, pan-enteric CE is better tolerated than ileocolonoscopy because of procedure related discomfort and embarrassment during the latter [13, 16].

Few studies have assessed the bowel cleansing level and diagnostic performance of pan-enteric CE in patients examined for CD. In a study by *D'Haens et al.* including 40 patients with active CD in the colon, 84% of segments had a diagnostic image quality [13]. The cleansing level was assessed in separate colonic segments, however, as opposed to an overall assessment used in our study. *Leighton et al.* compared colon CE with ileocolonoscopy in 66 patients with active known CD [14]. The percentage of patients with a good or excellent bowel cleansing in 5 colonic segments ranged from 39% to 63%, which was significantly lower than for ileocolonoscopy. However, both the per-patient and per-segment diagnostic yield was superior with CE. This emphasizes that detection of Crohn's lesions is not strictly dependent on an optimal image quality. In the study by *Bruining et al.*, 64% of patients achieved a good or excellent bowel cleansing in the colon [15]. *Oliva et al.* compared colon CE with ileocolonoscopy, MRI and ultrasound in 40 pediatric patients with known CD [16]. A good or excellent bowel cleansing was achieved in 76% of patients. All studies used a bowel cleansing regimen similar to the present study, i.e. 4 L of PEG in a split dose plus variable types of booster preparations. However, none of the studies reported the adherence to the regimen. Also, studies included patients with known CD compared to suspected CD in this study which could influence the adherence, image quality and diagnostic yield.

The present study examined the adherence to the recommended bowel cleansing regimen, clinical factors affecting the obtained image quality and the diagnostic yield of pan-enteric CE in patients with suspected CD. A minority of patients were able to ingest the total volume of PEG (17%) while 75% were able to drink more than 2 L. The majority of patients examined for CD report diarrhoea as a dominant symptom. We were not able to confirm our hypothesis, however, that stool frequency and consistency affects the image quality. The ingested volume of PEG was the single factor affecting the degree of bowel cleansing. Irrespective of the image quality, however, the diagnostic yield for

CD remained the same (43.9% and 47.1%). Hence, the majority of patients cannot complete the bowel cleansing and it affects the image quality, but the diagnostic yield remains the same. This is an important conclusion for the implementation of pan-enteric CE in clinical practice and in line with a limited number of studies examining the feasibility of low-volume bowel cleansing regimens [20-22].

There are some limitations to this study. Although the volume of PEG was recorded in this prospective, controlled and blinded multicentre study, we did not register the adherence to alerts during the CE procedure or the volume of ingested booster preparation. Also, it remains unknown if patients adhered to the diet and fasting rules prior to pan-enteric CE. These factors could influence the obtained image quality. Clinical data and C-reactive protein were obtained in close proximity to the CE procedure. However, faecal calprotectin was not measured immediately before the examination, and we did not apply a validated scale for stool consistency. These aspects could influence the analysis of factors associated with the obtained image quality.

In conclusion, pan-enteric CE is a promising new modality for non-invasive diagnosis of CD in patients without bowel obstruction. However, the extensive bowel preparation required to achieve a sufficient image quality is a major limitation. In the present study, the volume of PEG was the only factor affecting the image quality. Although few patients were able to ingest the recommended volume, the diagnostic yield was not affected. Future research should optimize and standardize the bowel cleansing regimen for patients examined for CD with pan-enteric CE.

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**Table 1:** Characteristics of 59 patients included in the study.

<b>Age (years)</b>	
Mean	31
Range	17-72
<b>Gender</b>	
Male	17 (29%)
Female	42 (71%)
<b>Height (cm)</b>	
Mean	171.5
Range	159-190
<b>Weight (kg)</b>	
Mean	76.3
Range	48.8-120.0
<b>BMI</b>	
Mean	26.0
Range	18.9-45.2
<b>Smokers (n)</b>	16 (27%)
<b>Use of opioids or antidiarrheal drugs (n)</b>	3 (5%)
<b>No. of bowel movements</b>	
Mean	3.7
Range	(every 3 <sup>rd</sup> day – 17)
<b>Stool consistency (n)</b>	
Watery	27 (46%)
Alternating	20 (34%)
Normal	7 (12%)
Hard	5 (8%)
<b>C-reactive protein (mg/L)</b>	
Mean	9.1
Range	(0.6-58)
<b>Faecal calprotectin (mg/kg)</b>	
Mean	1067
Range	61-6000
<b>Bowel resection prior to inclusion in the study</b>	0 (0%)

**Table 2:** Multiple linear regression analysis examining the effect of clinical and biochemical variables on the degree of bowel cleansing.

<b>Variable</b>	<b>Coefficient</b>	<b>95% confidence interval</b>	<b>P-value</b>
Gender	0.13	-0.71 - 0.98	0.75
Age	0.00	-0.02 - 0.02	0.98
Height	-1.17	-5.69 - 3.36	0.60
BMI	0.05	-0.02 - 0.11	0.14
Smoking	0.00	-0.58 - 0.58	1.00
Stool frequency	-0.01	-0.10 - 0.09	0.89
Stool consistency	-0.29	-0.59 - 0.02	0.07
Use of opioids or antidiarrheal drugs	0.18	-0.57 - 0.94	0.62
C-reactive protein	0.01	-0.01 - 0.03	0.40
Faecal calprotectin	0.00	0.00 - 0.00	0.63
Inflammatory bowel disease	-0.25	-0.77 - 0.27	0.34
Total volume of ingested polyethylene glycol	0.47	0.23 - 0.71	< 0.001

*Bowel cleansing:* Poor 1 - fair 2 - good 3 - excellent 4

*Gender:* Female 0 - male 1

*Smoking:* No 0 - yes 1

*Stool consistency:* Hard 1 - normal 2 - alternating 3 - watery 4

**Figure 1:** Box plot showing the ingested volume of polyethylene glycol before pan-enteric capsule endoscopy. A split dose of 2 L in the evening and 2 L in the morning was recommended.





**Figure 2:** Volume of ingested Polyethylene glycol in patients with a fair, good or excellent bowel cleansing with pan-enteric capsule endoscopy.

