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The Visibility and Performance of Small Bowel Video Capsule Endoscopy With and Without Pre-Procedural Purge Preparation in the Same Patients

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ABSTRACT

Background: Small bowel (SB) video capsule endoscopy (VCE) is an established diagnostic tool for the investigation of SB pathologies. Despite clinical studies and a few meta-analyses, an area of continuing controversy is the role of pre-procedural bowel preparation.

Objectives: We compared the visibility and performance of VCE with and without purge preparation in the same patients.

Design: Post hoc analysis of randomized control trial.

Methods: This is a post hoc analysis of the prospective randomized CURE-CD Trial (Comprehensive individUalized pRoactive ThErapy of Crohn's Disease trial). Established Crohn's disease (CD) patients in clinical remission were enrolled and classified into two groups according to relapse risk assessment. All patients are followed up in our clinic and undergo laboratory tests every 3 months and serial VCE studies every 6 months. The first VCE is done after bowel preparation with a clear liquid diet, PEG, and laxative, whereas the subsequent VCEs, when disease is confined to SB only, are done after a day on clear liquid diet. The VCE visibility is rated (1–4 points) by a blind observer, unaware to the preparation regimen.

Results: Forty patients who underwent at least two VCEs, at baseline and after 6 months were included. Visibility scores were similar in these two time points (3.15 vs. 3.10, $p = 0.8$). Among the low-risk patients' group ($n = 16$) in whom the clinical parameters (CDAI, CRP, and fecal calprotectin) have not changed significantly during this period, Inflammatory scores assessed by the capsule Lewis score (LS) and PillCam-CD score (PCDS) were similar (median LS 225 vs. 225, $p = 0.87$, median PCDS 4 vs. 2, $p = 0.37$).

Conclusion: The visibility and performance of SB VCE for monitoring Crohn's disease is not significantly influenced by purge preparation.

Trial Registration: Clinicatrials.gov identifier: NCT03555058.

[Correction added on 05 May 2025, after first online publication: The author list has been updated to correct the order of the given names and surnames of all the authors, which had been incorrectly interchanged in the previous version.]

Summary

- There are conflicting data regarding whether a purgative preparation prior to VCE may improve its visualization and diagnostic yield.
- The present study is the first to compare intestinal visibility of VCE, with and without purgative preparation, in the same patient, and supports the randomized clinical trials showing no benefit for purgative preparation.
- In patients with Crohn's disease, VCE is used to assess small bowel involvement and monitor response to treatment. They are expected to undergo VCE several times in their lives, and therefore, the patient's convenience and compliance are of paramount importance.

1 | Background

Video capsule endoscopy (VCE) is a minimally invasive method for complete visualization of the small bowel (SB) mucosal surface, revolutionizing the investigation and diagnosis of SB pathology. The common indications for VCE include Crohn's disease, obscure gastrointestinal bleeding, celiac disease, chronic abdominal pain, and SB malignancy [1–3]. The diagnostic yield of VCE is largely dependent on image quality. Endoscopic visibility may be obscured by debris, intestinal secretions, and air bubbles. An effective bowel preparation prior to VCE may improve visualization and diagnostic yield of VCE. Prior studies have compared fasting (10–12 h), clear liquids, and various purgative bowel preparation regimens including polyethylene glycol (PEG), simethicone, sodium phosphate, and mannitol, but the optimal bowel preparation is controversial. Although several studies and meta-analyses support the use of purgative SB preparations to improve image quality and SB mucosal visualization [4–12], other conflicting studies suggest that a clear liquid regimen and pre-procedure overnight fast achieves adequate visualization with superior patient acceptability [13–18]. Possible adverse events of purgative bowel preparation include nausea, vomiting, abdominal pain, bloating, sleep disturbances, and electrolyte abnormalities. One methodological caveat of the available data is that all studies to date compared intestinal visualization between different groups of patients, making it hard to control for possible interindividual variability. The present study therefore aimed to compare intestinal visualization with or without purgative preparation within the same individual patient ingesting two VCEs within 6-month interval.

2 | Methods

This is a post hoc analysis of the prospective CURE-CD Trial (Comprehensive individUalized pRoactive ThErapy of Crohn's Disease trial, clinicatrials.gov identifier NCT03555058). The CURE-CD Trial investigates whether CD patients in remission, identified as having a high-risk for future flares or complications predicted by capsule endoscopy will benefit from proactive treatment guided by biologic drugs and therapeutic drug monitoring (TDM) to prevent these flares and maintain a long-lasting remission. CURE-CD is an ongoing prospective randomized three-arm controlled trial of adult CD patients in steroid-free remission (defined as Crohn's disease activity index [CDAI] of <150) for at least 3 months, but no more than 2 year (3–24 months' duration).

Patients undergo screening by MRE, patency capsule, and a baseline colonoscopy. Patients in whom patency of SB is proven, undergo VCE using the dedicated IBD-capsule (PillCam Crohn's). Patients with Lewis score >350 for worst SB segment are classified as high risk and are randomized for continued standard treatment or proactive treatment. Patients who are classified as low-risk patients, as per Lewis score <350 at baseline, will continue standard treatment. All the patients are followed up by clinic visits, physical examination, inflammatory and immune markers' assessment, and microbiome analysis every 3 months and by serial VCE studies and intestinal ultrasound every 6 months.

The first VCE (at baseline) includes both the small intestine and the colon and is done after bowel preparation by a clear liquid diet (for 24 h) and laxatives. If the disease is confined to SB only, subsequent VCEs are done after bowel preparation by a clear liquid diet (for 24 h) and 10 h fast before the test and includes only small intestine.

Bowel preparation before the first VCE until November 2019 included a clear liquid diet and administration of a purgative sulfate-free polyethylene glycol electrolyte lavage (SF-ELS) solution (e.g., PEG, Fortrans, and Solucion Bohm) divided into two doses: 1.5 L on the evening before the exam and 1.5 L on the morning of the exam day. Since January 2020, the purgative lavage had changed to two sachets of PICO-SALAX (10 mg sodium picosulfate) diluted in 1 L water each in order to improve patients' comfort.

As a part of a study, the degree of cleanliness is rated by a blinded observer, who is unaware to the manner of preparation a patient received. The cleanliness is rated according to a cleansing score of PillCam Colon Capsule formerly described [19] such as poor, fair, good, and excellent (Figure 1) by the same capsule reader unaware to capsule timing.

Clinical parameters such as gender, age, disease characteristics, number of bowel movements per day, CRP, and calprotectin were collected prospectively. Inflammatory assessment was expressed by the Lewis score (LS) in which the SB is divided into three parts by time (i.e., colonic entrance time minus duodenal entrance time divided into three) and PillCam-CD score (PCDS) in which the three parts are divided by their actual length.

3 | Statistical Analysis

Continuous variables are presented as median (interquartile range [IQR]) for skewed distribution. Categorical variables are expressed as count (percentage). Patients were grouped by capsule number (first capsule with bowel preparation and second capsule without bowel preparation). Categorical variables were compared using chi-squared analysis and Fisher's exact test. Non-parametric Wilcoxon paired tests were conducted to

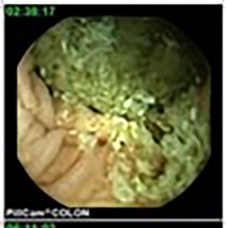
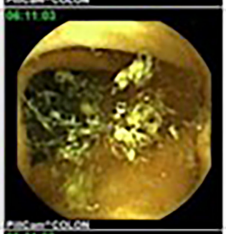
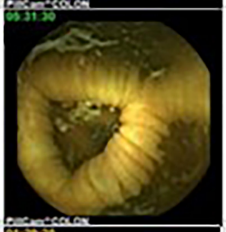
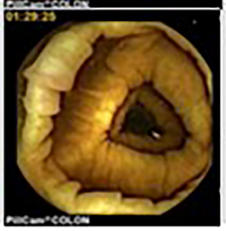
Cleansing level	Image	Description
Poor		Inadequate Large amount of fecal residue precludes a complete examination.
Fair		Inadequate but examination completed Enough feces or turbid fluid present to prevent a reliable examination.
Good		Adequate Small amount of feces or turbid fluid not interfering with examination.
Excellent		Adequate No more than small bits of adherent feces.

FIGURE 1 | Cleansing score for capsule endoscopy.

compare quantitative data. $p < 0.05$ was considered a statistically significant difference. All tests were two-sided. Statistical analysis was performed with SPSS (IBM SPSS Statistics, Version 25, IBM Corp., Armonk, NY, USA, 2016).

4 | Results

As of December 2021, 118 patients were screened for the study, 49 of which underwent at least two VCEs, at baseline and after 6 months. Six of them were excluded because they either did not receive purging material before first capsule (despite the protocol) or received purging material before the second capsule (in order to monitor colonic disease in non-isolated SB disease). Three patients experienced disease flare during the first 6 months and therefore were excluded. Overall, 40 patients were included in the present analysis: 16 patients in the low-risk group and 24 patients in the high-risk group. Table 1 shows the patients characteristics.

4.1 | Visibility Score

Visibility scores were similar in the two time points (3.16 vs. 3.10, $p = 0.7$) (Figure 2). When we checked the change in the visibility score for each pair of capsules of the same patient (second capsule's visibility score minus first capsule's visibility score), the change between capsules was between 1 and −1 in 95% of the pairs (Table 2).

4.2 | Diagnostic Yield

The chronological interval of 6 months between two VCE examinations makes it hard to compare the diagnostic yield, given that intestinal disease may change over time. Therefore, we restricted this analysis only to the patients in the low-risk group whose disease was less likely to progress during this short follow-up. Supporting this contention, the clinical status of patients in the low-risk group (i.e., baseline LS < 350), as expressed by CDAI, CRP, and calprotectin, has not changed significantly. When examining the diagnostic yield in this carefully selected subgroup, there was no significant difference in Lewis score or PCDS (Table 3) between VCEs done with or without preparation.

4.3 | Capsule Transit Parameters

Capsule termination site, that is, the site where the photographing of the capsule ended, was more distal in the first capsule, and small intestinal transit time was significantly shorter in the first capsule due to the use of purgatives (Table 4).

TABLE 1 | Patients' characteristics ($n = 40$).

Characteristic		*N* (%)/median (IQR)
Age, median (IQR)		23 (23–39)
Male, *n* (%)		29 (72.5%)
BMI, median (IQR)		23.1 (21.5–25.0)
Smoking, *n* (%)		5 (12.5%)
Age in diagnosis, median (IQR)		24 (20–33)
Disease location		
	Ileal	29 (72.5%)
	Colonic	0
	Ileocolonic	11 (27.5%)
	Upper GI	8 (20.0%)
SB location		
	Duodenum	0
	Jejunum	8 (20.0%)
	Non-TI ileum	19 (47.5%)
	TI	39 (97.5%)
Perianal disease, *n* (%)		1 (2.5%)
Disease behavior		
	Inflammatory	28 (70.0%)
	Stricturing	8 (20.0%)
	Penetrating	4 (10.0%)
Previous therapy		
	Steroids	13 (32.5%)
	5-ASA	8 (20.0%)
	IM	14 (40.5%)
	Anti-TNF	4 (10.0%)
	Vedolizumab	1 (2.5%)
	No therapy	14 (35.0%)
Current therapy		
	5-ASA	2 (5.0%)
	IM	0 (0.0%)
	Anti-TNF	25 (62.5%)
	Vedolizumab	1 (2.5%)
	No therapy	11 (27.5%)

Abbreviations: BMI, body mass index; GIT, gastrointestinal tract; IM, immunomodulators; IQR, interquartile range; TI, terminal ileum.

5 | Discussion

In this post hoc study, we evaluated two different pre-VCE SB preparation protocols in the same group of patients at two time points, as a part of the prospective CURE-CD study. We found no significant difference in SB visibility on VCE between clear fluid diet preparation and purgative preparation. The diagnostic yield as gauged by the Inflammatory scores (LS and PillCam-CD score) of the low-risk group at these two time points was similar, in line with their stable clinical and biomarker parameters. In contrast, the clinical indices of the patients in the high-risk group (i.e., baseline LS > 350), which were more aggressively treated, improved during 6 months. Accordingly, the findings in the capsule changed significantly between these two time

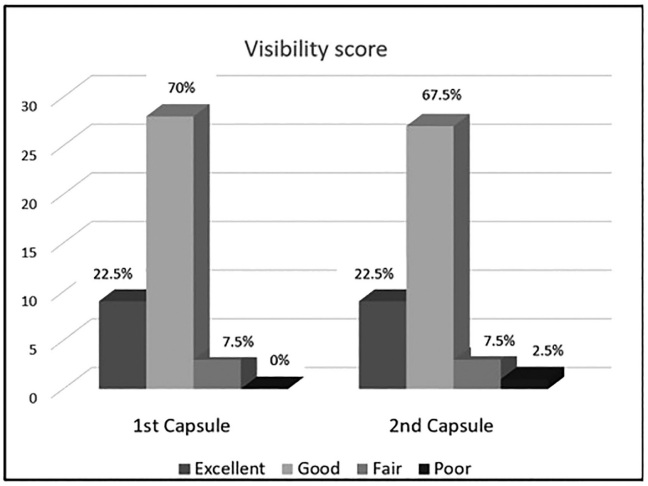


FIGURE 2 | Visibility scores ($n = 40$).

TABLE 2 | Visibility score delta ($n = 40$).

Visibility score delta	*n* (%)
1	9 (22.5%)
0	23 (57.5%)
−1	6 (15.0%)
−2	1 (2.5%)
−3	1 (2.5%)

TABLE 3 | Low-risk patients' clinical parameters and capsule parameters ($n = 16$).

Clinical parameters			
Parameter	**1st visit**	**2nd visit**	***p***
Total CDAI, median (IQR)	57 (29–72)	31 (15–90)	0.650
CRP g/dL, median (IQR)	1.3 (0.6–3.8)	1.3 (0.8–2.7)	0.501
Fecal calprotectin mcg/g, median (IQR)	46 (30–173)	85 (42–192)	0.221
Capsule parameters			
Parameter	**1st capsule**	**2nd capsule**	***p***
Highest Lewis score, median (IQR)	225 (135–225)	225 (0–225)	0.877
Total SB Lewis score, median (IQR)	315 (135–450)	225 (0–518)	0.900
Total SB PillCam-CD score, median (IQR)	4 (4–6)	2 (0–7)	0.377

Abbreviations: CRP, C-reactive protein; CDAI, Crohn's Disease Activity Index; IQR, interquartile range.

TABLE 4 | Capsule transit parameters ($n = 40$).

Parameter		**1st capsule**	**2nd capsule**	***p***
Capsule termination site, *n* (%)				
	Cecum	0	10 (25.0%)	0.001
	Rectum	17 (42.5%)	19 (47.5%)	
	Toilet	23 (57.5%)	11 (27.5%)	
Transit time (min), median (IQR)				
	GTT	51 (22–93)	56 (25–91)	0.882
	SBTT	132 (105–191)	235 (161–309)	0.002

Abbreviations: GTT, gastric transit time; SBTT, small bowel transit time.

points, and as a result, it was not possible to compare and draw conclusions regarding the effect of the preparation on the diagnostic yield.

Since its invention two decades ago, the use of VCE has become common in the diagnosis of various pathologies in SB, and as in endoscopy, the degree of accuracy depends on the degree of visibility.

At first, it was commonly thought that a purgative material should be used in preparation before VCE to allow good visibility, but this is in constant controversy in the literature over the years. A growing body of evidence suggests that a clear liquid bowel regimen or clear liquid diet and fasting prior to VCE produces equivalent image quality results and is better tolerated by patients.

Ben-Soussan et al. [15] retrospectively reviewed 42 patients who received either 2 L PEG bowel preparation or were fasting prior to VCE. No significant differences in image quality or capsule completion rate were found between the two groups; however, the PEG preparation group had a longer GTT. These results were further supported by a randomized, prospective, multicentre study [16] in which 291 patients were randomized to 4 L of clear liquids, 4 L PEG, or sodium phosphate. There was no significant difference in bowel cleanliness or diagnostic yield between the three groups, and the clear liquid regimen was better tolerated by patients.

A large retrospective study in two tertiary care centres by Klein et al. [20] compared 360 VCE procedures in which the bowel was prepared with 2 L PEG was compared to 500 VCE procedures in the other centre, which were prepared with a clear liquid diet plus 12-h fast. Bowel preparation quality and overall positive SB findings were similar between the two groups. SB completion rates were higher in the PEG protocol, and SB passage time was significantly faster in the PEG protocol. These findings have been corroborated by a recent prospective, randomized controlled study [21]. In this study, 198 patients were randomized

to clear liquids, sodium picosulfate and magnesium citrate, or 2 L PEG prior to VCE. There was no difference in diagnostic yield between the three groups, and the clear liquids regimen was better tolerated by patients. Most recently, prospective multicentre controlled trial of 834 patients with suspected SB bleeding compared clear liquid diet with two different PEG-based bowel preparation methods. SB cleansing was improved with PEG preparation, but no significant difference was observed for detection of clinically relevant SB lesions [22].

Several meta-analyses have also evaluated the benefit of a purgative bowel cleansing prior to VCE. A meta-analysis of 40 studies [10] demonstrated that a laxative bowel preparation prior to VCE did not improve diagnostic yield of small bowel findings (significant and overall) nor the capsule completion rate. However, SB visualization quality was improved in patients who received a laxative bowel preparation. Thus, it has been suggested that the use of laxatives may be beneficial in patients likely to have subtle findings. A more recent meta-analysis of 12 randomized controlled trials [23] revealed that purgative bowel preparations did not improve diagnostic yield, mucosal visualization quality, gastric transit time, SB transit time, or completion rate when compared to a clear liquids preparation prior to the exam.

Although the aforementioned studies included larger numbers of patients than in the present trial and some have randomized patients to purgative or not, none of the previous studies has compared visibility with or without purgative in the same individual patient, therefore potentially introducing interindividual confounders that are hard to definitively exclude. The present study, to the best of our knowledge, is the first to compare intestinal visibility in the same patient, whether with or without purgative preparation, and supports the randomized clinical trials showing no benefit for purgative preparation.

Several considerations make our findings pertinent to Crohn's disease patients, in particular. In patients with Crohn's disease, the capsule is used to assess SB involvement and monitor response to treatment; thus, Crohn's patients are expected to undergo a VCE several times in their lives, and therefore, patient's convenience and compliance are of paramount importance. In addition, in patients with Crohn's, the main findings such as ulcers, aphthae, and mucosal edema are multiple; thus, the chance of a false negative error is minimal, as compared to patients with obscure GI bleeding in which one may find only a few significant lesions.

Our study has several limitations: Firstly, the study was primarily limited to patients with known Crohn's disease and inflammatory findings, and not with other pathologies such as vascular lesions, polyps, and bulging. On the other hand, there were no other significant findings that were noted, and obviating the need for purgative preparation for Crohn's patients undergoing VCE, clinically relevant message in these patients inflicted with a chronic disease and need for lifelong monitoring.

Secondly, with regard to the examiner's blindness, it can be argued that the first capsule can be identified by including the colon. On the other hand, the reader was unaware of the identity of the patient or the patient's previous capsule's findings, and the rating was made as part of a routine capsule reading protocol with no primary aim to compare the level of cleanliness.

Thirdly, in this study, all capsules were read by a single reader, with over 15 years of capsule reading experience. Although this supports data uniformity, it does not allow to address potential interobserver variability of rating and caution may be needed in generalizing the findings to less experienced VCE interpreter clinicians.

Finally, our study was retrospective and based on a small sample size of only 40 patients in each group. To prove noninferiority, it is preferred, but not mandatory, to conduct a prospective study, and a larger sample size is required.

In conclusion, the visibility and performance of small bowel VCE is not significantly influenced by purge preparation in detecting inflammatory findings at patients with Crohn's disease.

Acknowledgments

The authors have nothing to report.

Ethics Statement

This is a post hoc analysis of CURE-CD Trial (Comprehensive individUalized pRoactive ThErapy of Crohn's Disease trial), clinicatrials.gov identifier NCT03555058. The study was approved by Sheba IRB committee on November 30, 2018 (approval number 4945-18-SMC). The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's Human Research Committee. Written, informed consent was obtained from each patient included in the study.

Conflicts of Interest

S.B.H. has received consulting and advisory board fees and/or research support from AbbVie, MSD, Janssen, Takeda, and CellTrion. U.K. has received speaker fees from Abbvie, Janssen, and Takeda; research support from Takeda and Janssen; and consulting fees from Takeda and CTS. A.E. has received advisory and/or research support from Abbvie, Janssen, Takeda, and Medtronic. R.M.Y. has received consulting fees from Medtronic. B.U. received consultation fees from Neopharm, Takeda, Janssen, and AbbVie. The other authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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