

PillCam COLON 2[®] as a pan-enteroscopic test in Crohn's disease

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Abstract

A recent paper by Boal Carvalho *et al* demonstrates the potential of PillCam COLON 2[®] (PCC2) as a pan-enteric investigation in Crohn's disease (CD). Our own prospective data in patients with known CD also shows good correlation between PCC2 and small/large bowel investigations ($R = 0.896$, $P < 0.0004$ / $R = 0.6667$, $P <$

0.035). Larger studies are warranted to prospectively validate the use of PCC2 in the investigation and monitoring of both small and large bowel CD.

Key words: Capsule endoscopy; Panenteroscopy; Small bowel Crohn's disease; Mucosal healing; Colon capsule

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Core tip: Mucosal healing has been shown to reduce the need for surgery and hospitalisation in patients with Crohn's disease. Currently, assessing small bowel and colonic mucosal healing requires separate imaging/endoscopic modalities. Recent data suggests that the PillCam Colon 2[®] (PCC2) is capable of assessing mucosal healing of the small intestine and colon in a single, non-invasive test. Our own prospective data corroborates these findings demonstrating good correlation between investigations. Larger studies assessing the viability of PCC2 as a pan-enteric investigation are warranted.

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TO THE EDITOR

We read with interest the recent article by Boal Carvalho *et al*^[1] entitled "PillCam COLON 2[®] in Crohn's disease: A new concept of pan-enteric mucosal healing assessment". Mucosal healing in Crohn's disease (CD) remains a current hot topic. Numerous colonic studies suggest that mucosal healing leads to increased steroid-free remission and decreases surgical and hospitalisation rates^[2-5]. More recent studies have established that small bowel capsule endoscopy (SBCE) is capable

Table 1 Bowel preparation regime for study participants undergoing same day colon capsule and colonoscopy

Schedule	Intake
Day 1	
All day	10 glasses of water throughout the day
Evening	Four senna tablets
Day 2	
All day	Clear liquid diet
Evening	2l Klean prep
Day 3 (exam day)	
Morning	2l Klean prep
10-11 am	Colonoscopy + capsule ingestion
1 st boost (upon small bowel entry)	1 sachet sodium picosulfate
2 nd boost (4 h later)	1 sachet sodium picosulfate

of safely monitoring small bowel mucosal healing^[6,7] although long-term follow up studies are required to demonstrate the efficacy of small bowel mucosal healing. The use of PillCam COLON 2 (PCC2) as a pan-enteric device has been previously investigated by Negreanu *et al*^[8].

This current study by Boal Carvalho *et al*^[1] again demonstrates the potential of PCC2 as a "one-stop", non-invasive mucosal healing assessment of both the large and small bowel. In total, 12 patients were enrolled in the study. Each patient underwent an ileocolonoscopy and SBCE at diagnosis. All patients had a PCC2 performed following one year from diagnosis. The aim was to evaluate the ability of PCC2 to assess mucosal response to therapy in both the large and small bowel. At one year, mucosal healing of the small bowel and large bowel was 33% and 50%, respectively. The combined mucosal healing rate was only 25%. However, perhaps most importantly, PCC2 was shown to be capable of adequately assessing both small and large bowel CD.

Our own data would appear to support these findings in terms of the viability of PCC2 as a pan-enteric device. We performed a prospective comparative study of PCC2 vs both ileo-colonoscopy and SBCE in patients with known CD. Following ethical approval, patients were recruited from our clinic at Tallaght hospital over a 6-mo period. Major exclusion criteria included known small bowel stricture, recent gastrointestinal surgery (within 3 mo of study recruitment) and chronic NSAID use or NSAIDS within 6 wk of study recruitment (apart from 5-ASA therapy). SBCE and PCC2 investigations were performed using PillCam technology (Given Imaging, Yoqneam, Israel). SBCE followed our standard protocol without bowel preparation. PCC2 and colonoscopy were performed no longer than 14 d following SBCE. Bowel preparation regimen was performed over a 3 d period (Table 1). One experienced endoscopist performed all study colonoscopies. PCC2 was performed on the same day as ileo-colonoscopy. All SBCE and PCC2 images were reviewed by two clinicians experienced in reading and interpreting capsule examinations. The capsule endoscopy CD activity index (CECDAI) was utilised to assess the severity of disease activity. The

Table 2 Baseline characteristics of study patients (*n* = 10)

Median age in years (range)	31 (19-47)
Female	7 (70%)
Smoker	5 (50%)
Disease extent	
Ileo-colonic	10 (100%)
Disease subtype	
Inflammatory	4 (40%)
Stricturing	6 (60%)
Previous resection	
Ileo-caecal surgery	4 (40%)
Ilealsurgery	1 (10%)
Medications	
Thiopurine	3 (30%)
Biologic	9 (90%)

CECDAI divides the small bowel into proximal and distal segments and uses three major criteria to grade severity: Inflammation, extent of disease and the presence of stenosis with the addition of proximal and distal scores leading to an overall CECDAI score. The authors utilised the CECDAI score for this study due to the fact that it is the only capsule scoring system which has been prospectively validated to date^[9]. Activity was graded as follows; inactive disease (CECDAI = 0), mild disease activity ($3.5 < \text{CECDAI} < 5.8$), moderate to severe disease activity ($\text{CECDAI} \geq 5.8$). Colonic disease activity was based on the Simple Endoscopic Score for Crohn's Disease (SES-CD); inactive disease (SES-CD = 0-3), mild disease activity (SES-CD = 4-10), moderate disease activity (SES-CD = 11-19) and severe disease activity (SES-CD ≥ 20).

In total, 10 participants were enrolled; median age of 31 years (range 19-47), 7 (70%) female. Every participant had previously documented ileo-colonic disease. Baseline demographics are summarised in Table 2. All capsules reached the caecum ensuring complete small bowel views for both SBCE and PCC2. Overall image quality was adequate for both modalities. Upon review of SBCE images, 2 (20%) had no small bowel disease activity, 5 (50%) had mild/moderate severity with the remaining 3 (30%) having severe small bowel CD. In terms of disease distribution, the majority 7 (88%) had distal ileal disease only with only one (12%) participant having evidence of more proximal small bowel disease. In comparison, PCC2 detected the following disease activity; 2 (20%) normal, 6 (60%) mild/moderate with the remaining 2 (20%) having severe disease. There appeared to be good correlation between SBCE and PCC2 images in terms of the recognition and grading of disease activity ($R = 0.896$, $P < 0.0004$). The caecal intubation rate for colonoscopic procedures was 100%. Overall, the terminal ileum was intubated in 9 (90%) participants. All CCE procedures successfully reached the rectum. Of note, there were no complications with any of the capsule or colonoscopic procedures. On colonoscopy, 8 (80%) had no disease activity with 2 (20%) having mild disease. The majority of participants (9, 90%) had

no disease activity on PCC2 with only one participant meeting the criteria for mild disease activity. There was good correlation between the two modalities ($R = 0.6667$, $P < 0.035$).

Despite limited numbers between all of the studies performed to date, PCC2 does appear capable of successfully examining the small and large bowel and also accurately detecting small bowel and colonic CD. With regard to our own data, PCC2 did appear to miss disease in the proximal small bowel that was detected by SBCE. This may be due to the PCC2 technology itself which "shuts down" in the proximal small bowel to conserve battery life. Alternatively, reader error may be at fault. The development of a "pan-enteric" capsule designed specifically for both small and large bowel imaging may ultimately be required. In terms of colonic disease, the correlation between modalities was not quite as strong as that witnessed for small bowel images. However, this may be due to the scoring system utilised. There was discrepancy between PCC2 and colonoscopic disease activity scores in only two participants. The actual numerical difference in the SES-CD scores for both participants was a solitary point. In both cases, this increased the disease severity into a higher bracket of disease activity which likely skews the correlation between the two modalities. The development of a combined scoring system encapsulating both small and large bowel disease activity may be a viable option in the progression of this technology. Certainly based on the evidence to date, larger studies are warranted to prospectively validate the use of PCC2 in the investigation and monitoring of both small and large bowel CD.

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