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Therapeutic impact of colon capsule endoscopy with PillCam™ COLON 2 after incomplete standard colonoscopy: a Spanish multicenter study

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ABSTRACT

Introduction: Colon capsule endoscopy (CCE) is an alternative approach for the examination of the colon in patients who refuse colonoscopy or after incomplete colonoscopy (IC). We conducted a study to determine the frequency of complete colonoscopy after IC, the diagnostic yield of CCE, the therapeutic impact of lesions

found in CCE, the level of colon cleanliness and the safety of the procedure.

Methods: We performed a prospective, multicenter study involving ten Spanish hospitals. Consecutive outpatients aged ≥ 18 years with previous IC were invited to participate. The latest version of the CCE device, PillCam™ COLON 2 (CCE-2), was administered to all patients according to the protocol.

Results: The study population comprised 96 patients. The most frequent cause of IC was the inability to move past a loop using standard maneuvers (75/96 patients, 78%). Complete visualization of the colon was obtained with CCE-2 in 69 patients (71.9%). Of the 27 patients in whom the CCE-2 did not reach the hemorrhoidal plexus, it passed the colonic segment explored with the previous colonoscopy in 20 cases; therefore, it could be inferred that a combined approach (CCE-2 plus colonoscopy) enabled complete visualization of the colonic mucosa in 92.7% of patients. CCE-2 revealed new lesions in 58 patients (60.4%). Polyps were the most frequent finding (41 patients; 42.7% of the total number of patients). In 43 of the 58 patients (44.8% of the total number of patients), the new lesions observed led to modification of therapy, which included a new colonoscopy for polyp resection or surgery in patients with colonic neoplasm.

Conclusions: CCE-2 is a suitable diagnostic procedure that can lead to more frequent diagnosis of significant colonic lesions after IC.

Key words: Capsule endoscopy. Colonoscopy. Colonic polyps. Colonic neoplasms. Colonic diverticulosis.

INTRODUCTION

Colonoscopy is the gold standard approach for the examination of the colon, enabling both diagnostic and therapeutic interventions (1). The frequency of incomplete colonoscopy (IC) has been reported to be 5-24% (2). The main causes of IC include fixed or long loops, redundant or tortuous sigmoid colon, severe diverticular disease, adhesions in patients with previous abdominal surgery, obstructive colorectal cancer, poor bowel cleansing and discomfort in non-sedated patients (3). Data support the role of an additional procedure to complete the examination of the colon in order to rule out lesions in segments not viewed. One study (4) showed that about 4.3% of

patients with IC had an advanced colorectal neoplasm that would have been missed if additional imaging had not been performed. There is no consensus on the most appropriate second option for the examination of the colon in patients with IC. The various options include the following: a) repeating the colonoscopy with a more experienced operator, improving the bowel preparation and/or using different endoscopes (pediatric or variable stiffness colonoscopes, balloon-assisted enteroscopes); b) deep sedation in previously non-sedated patients; and/or c) additional imaging studies (computed tomography colonography, barium enema and colon capsule endoscopy [CCE]) (5,6). CCE seems to be a useful alternative when IC is due to a non-occlusive cause (malignant or benign colonic strictures) because of its harmlessness and ability to detect various types of colonic lesion. The latest CCE device from PillCam, the PillCam® COLON 2 (CCE-2), enables images to be acquired at a rate of up to 35 images per second (both domes), and offers 172° coverage of the colon (from each dome). A meta-analysis (7) evaluating five CCE-2 studies revealed a pooled sensitivity and specificity of 87% (95% confidence interval [CI], 77%-93%) and 76% (95% CI, 60%-87%), respectively, for the detection of a colorectal polyp measuring at least 6 mm, and a pooled sensitivity and specificity of 89% (95% CI, 77%-95%) and 91% (95% CI, 86%-95%), respectively, for the detection of a colorectal polyp measuring at least 10 mm. Based on limited published data, in 2012, the European Society of Gastrointestinal Endoscopy recommended CCE as a feasible and safe tool for the visualization of the colon in patients with incomplete colonoscopy without obstruction (8). The main aim of our study was to determine the frequency of complete colonoscopy after an IC. The secondary objectives were as follows: a) to evaluate the diagnostic yield of CCE-2 in detecting colonic lesions in the unexplored segments; b) to determine the diagnostic yield of CCE-2 in detecting lesions in parts of the colon that were visualized in the previous IC; c) the impact of CCE-2 on therapy; d) to test the level of colon cleanliness; and e) to evaluate the safety of the CCE procedure.

PATIENTS AND METHODS

We performed a prospective, non-randomized, multicenter study involving ten Spanish hospitals. Patients were included from November 2010 to April 2013. Written

informed consent was obtained from all patients.

Inclusion criteria

All eligible outpatients aged ≥ 18 years with previous IC were invited to participate in the study.

Exclusion criteria

The exclusion criteria were as follows: a pacemaker or other implanted electro-medical devices, congestive heart failure, moderate to severe renal or liver impairment, pregnancy, known bowel obstruction, impediment to understanding bowel cleansing instructions, need for magnetic resonance imaging during the seven days after CCE-2, known allergy, and known contraindication to the study medications.

Definitions

Colonoscopy was defined as incomplete when cecal intubation was not achieved despite adequate bowel preparation (excellent or good) according to the 4-step Aronchick scale (excellent, good, fair and poor) (9). The location of the furthest point of advance of the colonoscope was recorded by the endoscopist in the colonoscopy report. No ink or clip marking was used.

CCE was considered to be complete when the capsule was expelled during the recording time or the hemorrhoidal plexus was visualized in the CCE-2 video review. Polyp(s) were considered as significant when they measured > 6 mm and/or when > 3 polyps were present.

CCE procedure

The capsule was swallowed within the 72 hours after IC in cases of suspected colorectal cancer (8/96 patients; 8.3%) or in a scheduled manner during the following week in other cases. Patients received oral and written instructions on bowel cleansing and had to follow a low residue diet two days before capsule ingestion, a clear liquid diet the day before the procedure, and a 4-l polyethylene glycol (PEG) split regimen (3 l the day before and 1 l on the day of CCE-2). Once the CCE-2 had entered the small

bowel, a booster preparation of sodium phosphate (Fosfosoda®) 30 ml was administered to achieve effective transit of the capsule through the small and large bowels; a second booster of Fosfosoda® was administered three hours after the first one if the CCE-2 was not expelled during this period. During the procedure, prokinetics (metoclopramide 10 mg IV or oral) were administered if the capsule stayed in the stomach for more than one hour, and a bisacodyl suppository was administered two hours after the second sodium phosphate booster if the CCE-2 was not expelled.

The CCE-2 examination used in the study comprised three elements: a) a disposable colon capsule, PillCam CCE-2 (Given Imaging Ltd., Yoqneam, Israel); b) a data recorder and real-time viewer (DR3); and c) review station software (RAPID station version 7). The CCE-2 examinations were reviewed in each participating institution. No central reading for CCE-2 examinations was required.

The study was approved by the local ethic committees.

Colonoscopy procedure

Previous ICs were performed by experienced endoscopists under sedation (unless the patient refused). The drugs used for sedation according to the hospital protocol were a combination of opioids (pethidine, fentanyl) and benzodiazepines (midazolam) or propofol infusion.

Statistical analysis

All statistical analyses were performed with SPSS, version 22.0. Descriptive tests were performed. The results of the efficacy analysis (findings detected by CCE-2) were reported for each patient. To reduce any bias effect, all eligible consecutive patients were included.

RESULTS

Patient baseline characteristics

The study population comprised 96 outpatients with previous IC who underwent CCE (31 male, 65 female) (Table I). Mean (SD) age was 58.06 years (14.2 years, range 22-86 years).

Optical colonoscopy

Colonoscopy was incomplete because of persistent loop formation in 75 cases (78%), patient intolerance in 12 (12.5%), and other causes (anatomical difficulties such as multiple diverticula) in nine (9.4%). IC revealed lesions in 34 patients (35.4%), the most frequent findings being diverticula in 15 (15.6%), polyps in 13 (13.5%), angioectasia in two (2.1%), ulcers in two (2.1%), and non-obstructive neoplasm in two (2.1%). The endoscopist was able to reach the ascending colon in 24 cases (25%), transverse colon in 16 (16.7%), descending colon in 19 (19.8%), sigmoid colon in 36 (37.5%) and rectosigmoid junction in one (1%).

Colon capsule endoscopy

CCE-2 examination was complete in 69 patients (71.9%) and incomplete in 27 (28.1%) (Fig. 1). The main causes of incomplete CCE-2 were difficult progression of the capsule in 19 patients, technical events (absence of recording due to interference and artifacts) in seven patients and intolerance to the booster preparation in one patient. Although the CCE-2 did not reach the hemorrhoidal plexus in 27 patients, it passed the previously visualized colonic segment in the colonoscopy in 20 cases (20.8%); therefore, it could be inferred that a combined approach (CCE-2 plus colonoscopy) enabled complete visualization of the colonic mucosa in 89 cases (92.7%). According to a standard system for grading bowel preparation (10), cleansing was considered as adequate (excellent or good) in 71 patients (74%), fair in 16 (16.6%) and poor in nine (9.3%) (Table II). CCE-2 revealed new lesions in 58 patients (60.4%) (Fig. 2) at locations not reached during the previous colonoscopy. Polyps (Fig. 3) were the most frequent finding (41 patients [42.7% of the total number of patients], significant in 25 cases [26%]), followed by diverticula (11 patients, 11.5%) (Fig. 4), colon cancer (two patients, 2.1%), angioectasia (two patients, 2.1%), and solitary colonic ulcers (two patients, 2.1%). In 43 of the 58 patients (44.8% of the total number of patients) the new findings modified the therapeutic approach: a new attempt at complete examination of the colon for polyp resection (using a balloon-assisted enteroscope, pediatric colonoscope or standard colonoscope and modification of the sedation protocol) was successful in

40 of the 43 patients. Of the three remaining patients with no resected polyps, one was referred for surgery and the other two were followed up owing to the finding of a single, benign polyp < 5 mm in the CCE-2 procedure. Two patients with colon cancer (in addition to the other two previously diagnosed patients) were referred for surgery based on the CCE-2 diagnosis. Secondary, minor changes in medication were made when colonic diverticula were found. Furthermore, in the CCE examinations that passed the furthest point of advance in the IC, all previously described colonic lesions were confirmed. One major event was recorded during the study. The patient was a 79-year-old man with no previous heart failure or other relevant history who experienced cardiorespiratory arrest that could not be reversed despite advanced cardiorespiratory resuscitation. The post mortem examination revealed undiagnosed severe dilated cardiomyopathy. The indication for CCE was anemia, and a post mortem capsule review revealed four angioectasias (3-5 mm each) in the ascending colon and cecum. No other relevant complications were described, and only eight patients (8.3%) complained of minor symptoms related to bowel cleansing (mild abdominal discomfort and nausea).

DISCUSSION

Colonoscopy is the standard procedure for investigation of colonic lesions. The cecal intubation rate ranges between 76.9% and 98.4% in some studies (2,4,8). CCE has the advantage of being a non-invasive test with no need for radiation that is generally well accepted by patients (11,12). We present a cohort of 96 consecutive patients with previous IC who required complete inspection of the colonic mucosa.

Completion rate

Our results show CCE-2 to be a suitable procedure in this group of patients. Using the CCE-2 capsule and a booster regimen (see above), we achieved direct complete visualization of the colon in 71.9% of cases, a percentage similar to that obtained in other CCE-2 studies (13), although lower than the standard for screening colonoscopy described in literature (between 90-95%) (14,15).

Cleansing level, excretion rate and findings

In order to improve patient compliance with the morning PEG intake, we used a 4-l split-dose PEG-based bowel preparation solution (3 l the day before and 1 l on the day of procedure) for bowel cleansing instead of the 2 l plus 2 l regimen recommended by the European Society of Gastrointestinal Endoscopy (5). Bowel cleansing was considered as adequate (excellent or good) in 75% of the patients. Bowel cleansing was poor in less than 10% of patients. Therefore, it seems that the regimen chosen had no negative consequences. Causes for this relatively low expulsion rate are not clear, since we used a booster protocol similar to that used in other studies (sodium phosphate [Fosfosoda®] and bisacodyl suppository if the capsule was not expelled). Administration of a booster is necessary to ensure that the capsule advances through the colon, and the best approaches have been discussed thoroughly. Spada et al. (16) compared a standard regimen (PEG + sodium phosphate) and a modified regimen in which sodium phosphate boosters were substituted with one or two PEG boosters, although the study showed that the use of sodium phosphate boosters achieved a 100% expulsion rate in < 10 hours, compared with 75% when it was not used. The mean colonic transit time was also increased 2-fold when sodium phosphate boosters were not used. A combined approach enabled completed visualization of the colonic mucosa in > 90% of the patients. These results show CCE-2 and colonoscopy to be adequate complementary procedures for examination of the colon, and CCE-2 combined with radiologic procedures could be a good alternative in patients with IC. Spada et al. (17) recently compared CCE-2 with CT-colonography in patients with IC and found no differences in the complete examination rate (98%), diagnostic yield (increased for CCE-2 in detecting polyps \pm 6 mm in the ascending colon) and level of bowel cleansing. Moreover, we confirmed that CCE-2 improved the detection of relevant colonic lesions. Polyps were the most frequent new finding, followed by diverticula and vascular lesions. More significantly, two colon cancers were diagnosed. Cases of polyps and colon cancer were referred for resection (endoscopy/surgery). These cases represented almost half of the patients with new findings in CCE-2. These results are in concordance with other previously reported (13,18,19). However, CCE-2 did not visualize new lesions in segments previously visualized using colonoscopy.

Safety

CCE is safe and generally well tolerated, with only minor complaints about the unpleasant taste of bowel cleansing solution and boosters. However, we recorded a severe event during our study, namely, the sudden death of a 79-year-old male with undiagnosed severe dilated cardiomyopathy. Consequently, cardiac and renal impairment must be evaluated in patients receiving phosphate solutions.

Limitations

Our study is subject to limitations. First, the furthest point of advance during the previous colonoscopy was not marked (with tattooing or clips), although the video review confirmed that the CCE-2 had passed the furthest point of advance in the IC. The reviewer had to ensure that the CCE-2 had surpassed the colon landmarks previously seen in IC (hepatic flexure image, splenic flexure image). Second, the lack of consistent follow-up means that no data are available for patients with negative findings, including those without optimal bowel cleansing. Third, not all patients with minor positive findings (diverticula, small vascular ectasias) underwent post-CCE colonoscopy to confirm these findings. In any case, all polyps and colon cancers were confirmed after additional colonic exploration using various types of endoscope (e.g., balloon-assisted enteroscope and pediatric colonoscope) or surgery. The optimal duration of the CCE examination has not been adequately addressed in the literature. We administered the CCE-2 following a protocol for logistic reasons. However, perhaps administration immediately after IC may be the best approach and could increase compliance. Further studies must address this issue.

In summary, the administration of CCE-2 can be an adequate alternative to complete the examination of the colon in patients with previous incomplete colonoscopy and could be considered as a good complementary procedure. The use of CCE-2 could increase the frequency of diagnosis of significant colonic lesions such as polyps or neoplasms that require specific treatment. All patients undergoing CCE require intensive bowel cleansing and administration of boosters to facilitate progression of the CCE through the colon. It is mandatory to search the medical history for heart or

kidney conditions.

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Table I. Patient baseline characteristics

Sex M/F, no.	31/65
Age \pm SD, y	58.06 \pm 14.2
Colonoscopy stopped at, no. (%)	
Ascending colon	24 (25%)
Transverse colon	16 (16.7%)
Descending colon	19 (19.8%)
Sigmoid colon	36 (37.5%)
Rectosigmoid junction	1 (1%)
Cause of incomplete colonoscopy, no. (%)	
Loop formation	75 (78%)
Patient intolerance	12 (12.5%)
Other	9 (9.5%)
Colonoscopy findings, no. (%)	
Normal	62 (64.6%)
Diverticula	15 (15.6%)
Polyps	13 (13.5%)
Angioectasia	2 (2.1%)
Ulcer	2 (2.1%)
Colorectal cancer	2 (2.1%)

Table II. Grading of bowel preparation for CCE-2 exam

<i>Description of findings</i>	<i>Status</i>	<i>Grade</i>
No more than small bits of adherent feces	Excellent	1
Small amount of feces or dark fluid, but not enough to interfere with the examination	Good	2
Enough feces or dark fluid present to preclude a completely reliable examination	Fair	3
Large amount of fecal residue	Poor	4

Fig. 1. Colon capsule endoscopy. Complete visualization rate.

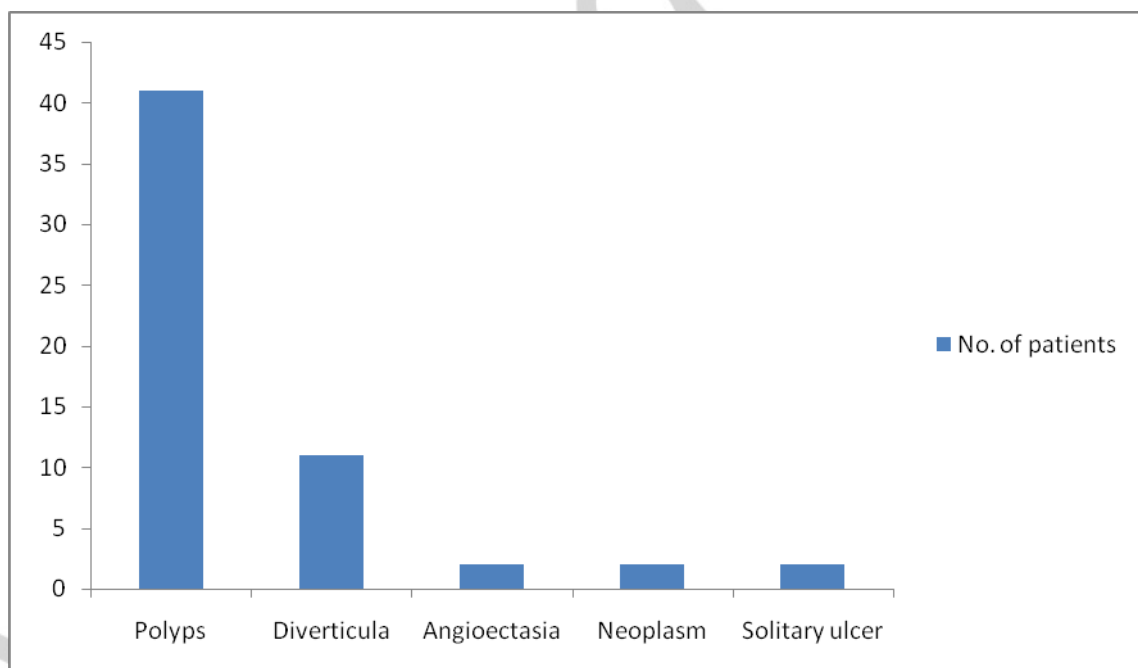


Fig. 2. Colon capsule endoscopy findings in previously unexplored colon segments.



Fig. 3. CCE image. Colon polyp.



Fig. 4. CCE image. Colon diverticula.