

Diagnostic yield and safety of capsule endoscopy

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ABSTRACT

Introduction: the capsule endoscopy (CE), from his approval, has become a first line diagnostic procedure for the study of the small bowel disease. The aim of this study is to report our experience since the implantation of this technique in our hospital.

Material and methods: retrospective review of the CE undertaken in Department of Endoscopy. There was gathered in every case the age, sex, motive of consultation, previous diagnostic procedures, capsule endoscopy findings and complication of the technique. One took to end a descriptive and analytical analysis.

Results: there was achieved a total of 416 explorations in 388 patients. The obscure gastrointestinal bleeding was the most frequent indication (83.30%) followed by suspected Crohn's disease (7.5%). Angiodisplasia was the endoscopic lesion more frequently detected (42.2%), especially, in patients with digestive bleeding of obscure origin (OR 3.13 p < 0.001), followed by the flebectasia (10.6%) and the ulcer suspicious of Crohn's disease (9.9%). The global diagnostic yield as for the detection of injuries was 77.34% with a case of "not defecation of the capsule" and therefore need of laparotomy.

Conclusions: the capsule endoscopy is a technique consolidated and as his potential is known, his indications are extended. The obscure gastrointestinal bleeding is the most frequent indication and the angiodisplasia the most identified injury. Once known his diagnostic yield, larger studies are needed that assess the influence of capsule endoscopy on clinical outcomes.

Key words: Capsule endoscopy. Obscure digestive bleeding. Occult gastrointestinal bleeding. Iron deficiency anemia. Crohn's disease.

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INTRODUCTION

Capsule endoscopy (CE) has become a first-rate diagnostic procedure for the study of small bowel (SB)-related diseases (1-4). Since the technique was approved by the FDA (August 2001), its indications have varied as its potential diagnostic power and possible repercussions on subsequent therapeutic attitudes became known.

Nowadays the main indication of the CE is gastrointestinal bleeding of obscure origin (OGB), either in the form of occult bleeding (iron-deficiency anemia, positive occult blood in feces) or manifest bleeding where blood is visible, although no cause has been identified even after upper and lower endoscopic examinations (5-12).

Another confirmed indication is Crohn's disease (CD), although it may be primary contraindicated because of stenosis and it has the limitations of absence of histological confirmation and a difficult differential diagnosis with other conditions with similar characteristics (12,13).

Other indications for CE are: SB tumors, predominant and generally discovered in the context of OGB, or suspected based on some imaging studies; gastrointestinal polyposis (14), malabsorption and eventually abdominal pain or symptoms of irritable bowel syndrome after some study on diagnostic effectiveness (3). In number of studies, CE has demonstrated better global results than other diagnostic methods, such as push enteroscopy, enteroclysis or conventional bowel follow-through, which also evaluate the SB (13,15).

After approval by the European Agency in August 2001, it began to be used in daily clinical practice at our hospital as a reference center.

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The aim of the present study is to report our experience with the CE since this procedure was implemented in our hospital, emphasizing its indications and diagnostic performance.

MATERIAL AND METHODS

A retrospective analysis of all CEs performed between November 2001 and January 2005 at the "Hospital Clínico San Carlos", Madrid, was carried out.

The following data were noted for each patient: age, sex, origin, reason for consultation, previous diagnostic procedures, endoscopic diagnosis, and incidents inherent to the technique.

All examinations were carried out using the M2A Given Imaging capsule following certain preparatory rules, including: fasting for 12 hours; no iron consumption for 10 days prior to the examination; no fruits, starch, vegetables or bread for 3 days before the test, and liquids only the day before.

As a general rule, no specific oral preparation was necessary, and prokinetics were administered to patients with founded suspicions of delayed passage, including bedridden and diabetic subjects. In each case, weight, height and waist measurements were taken and fed into the computer and recorder.

Guidelines followed for the examination were as follows:

1. Walk as much as possible and avoid sitting down for long periods or lying down.
2. Fasting for 3 hours, after which, some liquids (not dairy products) may be taken.
3. After 3 hours, a "light" snack may be taken with liquid.
4. 7 hours after capsule ingestion, the belt would be taken off and normal life could resume.
5. If the capsule has not been expelled within 1 week, the doctor must be consulted without undergoing any magnetic resonance procedures in the meantime.

All procedures were carried out with the written consent of the patient or legal representative where applicable, and the reading of studies was carried out by different doctors at the Endoscopy Department.

The program used for both the descriptive and analytical statistical studies was SPSS, version 12.0. Quantitative variables were expressed as mean \pm SD values; qualitative variables as percentages, and these variables were compared by means of a Chi-square test.

RESULTS

A total of 416 examinations were performed on 388 patients. Average patient age was 57.06 ± 18.20 years, with 50.5% being males and 49.5% females.

The reason for consultation was OGB [either in the

form of occult bleeding (50%) or in the form of manifest bleeding (33.30%)] in 83.30% of examinations. In the 7.5% of cases, CE was performed because of suspected CD, and, in another 4.6%, the cause was abdominal pain or diarrhea (Fig. 1). Regarding endoscopic diagnosis, angiodysplasia was the most commonly detected lesion (42.2%), followed by phlebectasia (10.6%) and ulcers suggestive of CD (9.9%) (Table I); in 11.8% of examinations, no pathological findings were found, and, in 3.8%, other diagnoses were established (two cecum neoplasms, 1 jejunal cancer, 1 carcinoid tumor, 1 Meckel's diverticulum, 2 Blue Rubber Bleb Nevus syndrome, 1 suspected case but not confirmed by histological study of Whipple's disease).

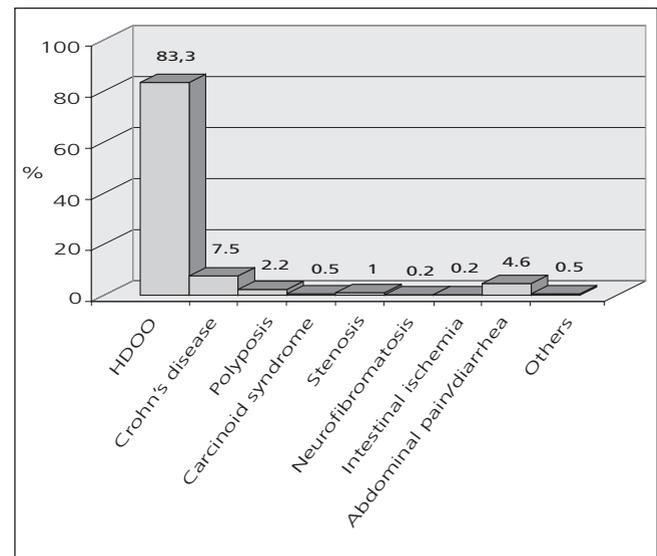


Fig. 1.- Reasons for consultation.
Motivos de consulta.

When the reason for consultation was OGB in the form of occult bleeding, angiodysplasia was the most frequently detected lesion (40.3%). However, in 12.6% of cases the test was normal. In case of manifest bleeding, angiodysplasia was also the most commonly detected lesion (55.9%), but in 5.9% of examinations CE showed normal findings. On a pooled examination of OGB, angiodysplasia was the most frequently observed lesion [46.5%, $p < 0.001$; OR, 3.13 (1.70-5.76)]. It is important to report that when the reason for testing was OGB, blood was found in the gastrointestinal tract in 12.9% of examinations [$p < 0.04$, OR 3.24 (0.98-10.78)].

On the analysis of cases with suspected CD, the most common endoscopic findings were bleeding ulcers suggestive of CD (26%) and angiodysplasia (26%). In 22% of examinations, the finding was normal. In the case of abdominal pain-irritable bowel-type symptoms (IBS), the examination was normal in 8 of them (42.10%) and inconclusive in another 2 cases (10.53%).

Table I. Endoscopic diagnosis

Diagnosis	%	Diagnosis	%	Diagnosis	%
Phlebectasia	10.6	Lymphangiectasia	5.3	Blood in stomach	1.7
Edema/inflammation	9.2	Submucosal tumor	2.4	Blood in bulb	0.7
Erosion	5.8	Stenosis	2.7	Blood in jejunum	3.9
Crohn's ulcer	9.9	Colonic ulcer	0.7	Blood in ileum	2.4
Aphthas	3.4	Intestinal varices	0.5	Blood in colon	2.9
Xanthoma	8.7	Nodular lymphoid hyperplasia	1.4	Slow transit	1.9
Angiodysplasia	42.2	Gastric polyp	1.2	Inconclusive	3.1
Lipoma	2.2	Small-bowel polyp	3.6	Technical difficulties	3.1
GAVE	0.7	Villous atrophy	1.7	Normal examination	11.8

Other diagnoses: 3.8%; GAVE: gastric antrum vascular ectasia.

Eleven cases (2.7%) were diagnosed with stenosis of the small bowel, of which 3 patients were examined for iron-deficiency anemia, another 3 for OGB in the form of melena, 2 for suspected CD, another 2 for abdominal pain or diarrhea, and 1 for suspected stenosis. A total of 9 examinations was carried out for polypoid syndromes such as familial adenomatous polyposis (FAP) and Peutz-Jeghers syndrome (PJS). In 2 cases (22.2%), gastric polyps were found; in one (11.1%), duodenal polyps, in 5 (55.5%), jejunal and ileal polyps; in 1 (11.1%), HNL, and in another patient the examination was normal.

In 88.43% of all examinations, the ileum was identified, but the capsule had not reached the colon after finishing its recording in 13.01% of studies. The degradable capsule "Patency™" was administered prior to the procedure in 5 patients with suspected stenosis of the SB: three patients (60%) excreted the capsule normally and, there-

fore, the study was subsequently carried out; another two patients (40%) did not excrete it, and one of them suffered from acute abdominal pain, which evolved favorably with conservative treatment.

Overall effectiveness with regard to the detection of lesions was 77.34%. In the case of OGB, the effectiveness was almost 80%; in CD, 68% and in abdominal pain, 42%. When we focus on findings that could be associated with symptoms overall effectiveness went down to 62%, and in the same way decreased in the three previous indications (66, 44 and 36% in OGB, CD, and abdominal pain, respectively) (Figs. 2 y 3).

There were 7 subjects (1.69%) in whom the capsule remained within the stomach when the recording was over; most were bedridden patients, three of them with a history of gastric surgery (Billroth II) where the capsule remained in the afferent loop. There were 2 cases

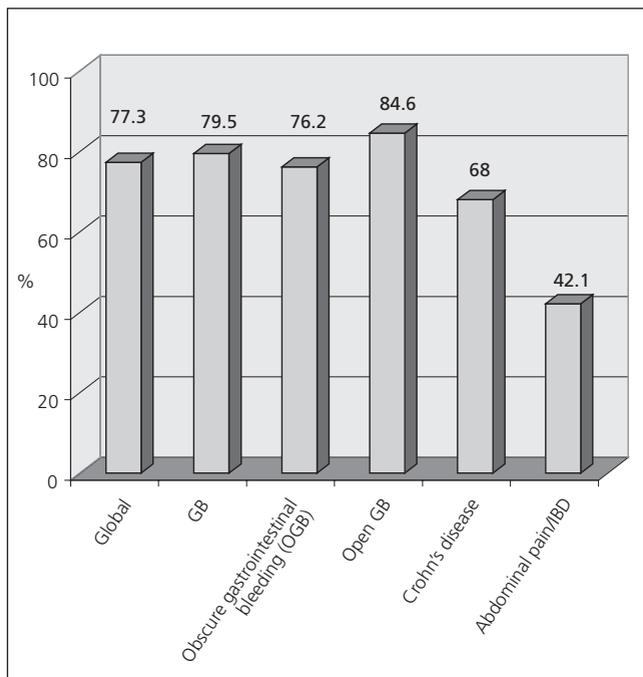


Fig. 2.- Effectiveness of capsule endoscopy in the detection of lesion. Rentabilidad de lesiones detectadas según indicaciones.

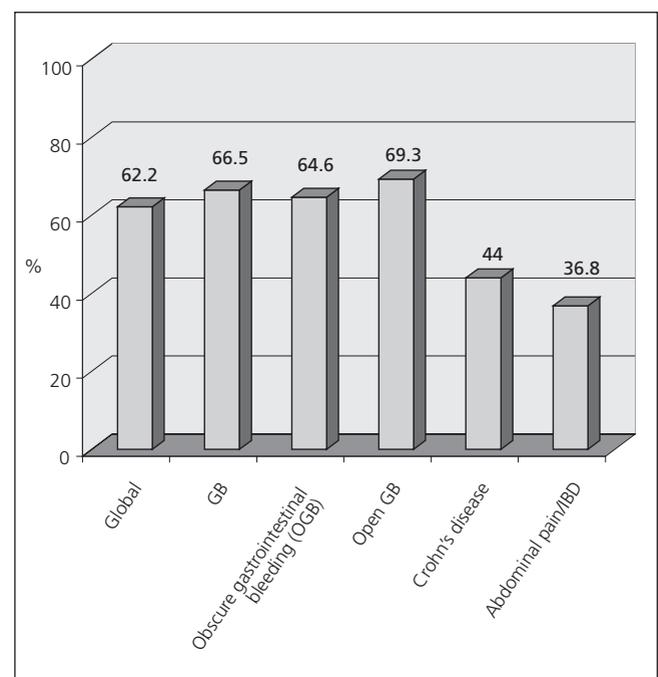


Fig. 3.- Effectiveness of capsule endoscopy based on its indications. Rentabilidad de lesiones diagnósticas según indicaciones.

(0.48%) of retention within the SB due to a stenosis of the intestinal loop, where the capsule could progress no further than the stenosis, and only one case was reported of "non-defecation of the capsule", which required a laparotomy.

Finally, we performed this examination in 13 patients (3.35%) carrying pacemakers. No interference or malfunction was observed in any of these patients in either way between the capsule and the pacemaker.

DISCUSSION

CE is a first-rate procedure for the study of small-bowel diseases that has become increasingly consolidated. Its indications have increased as its potential diagnostic and subsequent repercussions have been demonstrated.

Nowadays, OGB, either in the form of chronic anemia or in the form of manifest bleeding, continues to be the main indication for CE. In our study, OGB represented the 83.30% of all indications, of which 33.30% corresponded to manifest bleeding.

Angiodysplasia was the most frequent finding in our study (42.2% of total), corroborating the results from other studies, particularly when intestinal bleeding was the main symptom (16-18). It is a complex vascular lesion with a difficult diagnosis, which is attributed to 70-80% of SB hemorrhages. This percentage decreases when the study is carried out in younger patients.

In our study, the diagnostic effectiveness of CE was 77.34%, which is in the range of results published by others (40 and 75%). In the case of OGB, effectiveness varies between 55 and 75%, and in the case of CD between 43 and 70% (in our study, 79.53 and 68%, respectively) (12).

Regarding diagnostic effectiveness, certain clarifications and caution with results should be done. In practically all published studies, reference is made to lesions found whatever their nature and relationship with problem of the patient. Thus, the existence of blood in the gastrointestinal lumen is considered a positive finding even when no source of the bleeding could be identified. In this respect, it is essential to classify CE findings on the basis of the greater or lesser reliability with which the patient symptoms can be ascribed to these findings. The effectiveness of CE in OGB is clearly greater when bleeding is active when compared to occult bleeding (18-21). In tests performed in our hospital, the percentage of examinations with no findings was more than 2-fold for occult OGB as compared to manifest OGB. The same is the case with CD. In our study, overall effectiveness was almost 70%, but if we analyze lesions described as suggestive of CD (erosion, aphtas, ulcer, villi erosion, SB stenosis) effectiveness decreases to 44%. When the reason for consultation was abdominal pain, the objective effectiveness of CE was lower (in our study around 40% with an absence of findings in more than 50% of CEs) (3).

In different studies CE has demonstrated one way or another that it is superior to other diagnostic procedures

that also evaluate the SB –for instance, follow-through, enteroclysis, CT scans, and even push enteroscopy (7,8,12,13,15,22).

CE is quite a safe procedure allowing a complete view of the SB in a large percentage (88.43% in our study) of subjects; in quite a high percentage the capsule reaches the colon before the recording had finished (86.99% in our study), thus documenting in some cases a condition at this level when the gastrointestinal lumen does not have much fecal content (2,23).

Complications inherent to the technique are infrequent, but CE retention in the SB has been described (around 1% non-defecation of the capsule), in some cases, resulting in acute abdominal pain and, consequently, requiring urgent laparotomy (24). In our patients, one case of acute abdominal pain occurred, but it has been published a study in which it took place in 13.46% of laparotomies (25). The arrival of the Patency degradable capsule is aimed to prevent problems in patients with suspected stenosis, where CE is contraindicated.

We had not problems either in patients who had undergone previous abdominal surgery or in patients with pacemakers, which initially was considered a contraindication for the procedure. However, more recently, it has been demonstrated the absence of interference or malfunction of the pacemaker during the procedure (26,27). In our study we carried out 13 examinations on patients with pacemakers with no problems whatever.

Now that the diagnostic efficiency and safety of the capsule has been demonstrated, its clinical effectiveness regarding its relative use in later therapeutic interventions remains to be demonstrated. There are studies on this matter involving a small number of patients and with dissimilar results (9,15,28,29).

However, large scale studies on the clinical effectiveness of CE using a precise methodology are needed to allow its conclusive consolidation in clinical practice.

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