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ORIGINAL RESEARCH

Panenteric Capsule Endoscopy in Young Patients with Suspected Irritable Bowel Syndrome: A Self-Controlled Feasibility Study

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Objective: Although the diagnosis of irritable bowel syndrome (IBS) is based on clinical criteria, a colonoscopy is often performed to rule out alternative digestive disorders. The panenteric PillCam™ Crohn's capsule, which allows non-invasive examination of both the small bowel and the colon, may be an alternative investigation. We aimed to evaluate the feasibility of a strategy based on the panenteric capsule in combination with standard biological tests to exclude gastrointestinal disease in young adult patients with chronic abdominal symptoms suggestive of IBS as an alternative to the classical approach based on colonoscopy.

Design: Of 42 consecutive adults aged 18–50 years with symptoms consistent with IBS for more than 6 months, 33 were enrolled, and 27 received both routine biological tests, fecal calprotectin, panenteric capsule, and gastrointestinal endoscopies.

Results: All 21 lesions identified by the capsule in 15 patients were unrelated to digestive symptoms, as were the 11 lesions identified by colonoscopy in 7 patients, and all were of little or no clinical interest. In addition, one gastric ulcer and one gastric MALT lymphoma diagnosed only by systematic gastric biopsy were characterized by upper endoscopy. The capsule was preferred by all patients to the classical endoscopic procedures.

Conclusion: The diagnosis of IBS was not called into question in any of the patients explored. These preliminary results demonstrate the feasibility of a strategy based on the panenteric capsule in combination with standard biological tests to exclude gastrointestinal disease in young adult patients with chronic abdominal symptoms suggestive of IBS.

Plain Language Summary: Irritable bowel syndrome (IBS) is a disorder of gut-brain interaction characterized by abdominal pain and altered bowel transit without structural lesions explaining the symptoms. A diagnosis of IBS is clinical, but a colonoscopy can exclude other bowel disorders. Panenteric capsule endoscopy, an alternative to colonoscopy, noninvasively examines the small bowel and colon. We aimed to evaluate the feasibility of a strategy based on the panenteric capsule in combination with standard biological tests to exclude other gastrointestinal diseases in young adult patients with chronic abdominal symptoms suggestive of IBS as an alternative to the classical approach based on colonoscopy. Our study shows that the use of pancapsule in young adults with IBS symptoms is feasible, with all patients preferring the pancapsule over colonoscopy, indicating higher acceptability. Furthermore, lesions found by capsule and colonoscopy were unrelated to symptoms, and the IBS diagnosis remained unchanged, suggesting that the pancapsule was sufficient. In conclusion, pancapsule endoscopy could be a feasible alternative to colonoscopy for young adults with suspected IBS.

Keywords: irritable bowel syndrome, capsule endoscopy, panenteric capsule, PillCam™ Crohn's capsule, colonoscopy

Introduction

Irritable bowel syndrome (IBS) is a chronic digestive disorder characterized by abdominal pain and altered bowel transit that affects at least 5% of the general Western population.[1,2] Several subtypes of IBS are distinguished according to the

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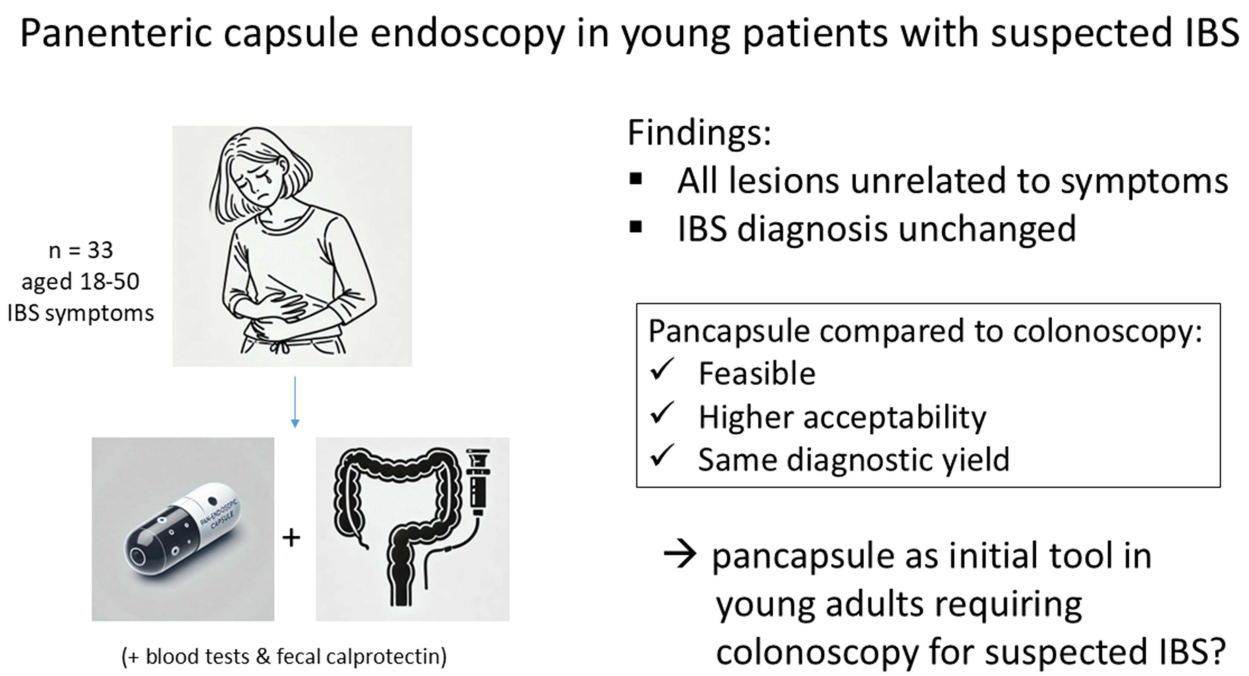
Graphical Abstract



predominant transit pattern: IBS-D (with predominant diarrhea), IBS-C (with predominant constipation), and IBS-M (a mixed form with alternating diarrhea and constipation). Irritable bowel syndrome is usually diagnosed before the age of 50 and affects more women than men. It is a common reason for consultation in both general practice and gastroenterology clinics. Although IBS is not a life-threatening condition, it can have a significant impact on quality of life, similar to or greater than other chronic conditions considered much more serious, such as depression or chronic end-stage renal disease.[3] This disorder is also a major economic burden for society due to high direct (visits, investigations, medication) and indirect (absenteeism and lost productivity) costs.[3]

In the absence of a diagnostic test, the diagnosis of IBS is based on clinical criteria and the exclusion of alternative diagnoses in some cases. In patients suspected of having IBS, particularly those with diarrhea, colonoscopy is often recommended in addition to standard biological tests to rule out alternative digestive disorders such as coeliac disease, inflammatory bowel disease (IBD), microscopic colitis, or neoplasia. A colonoscopy is also indicated in the presence of warning signs such as rectal bleeding, changes in bowel habits, nocturnal abdominal pain, or weight loss.[4] These signs are common in patients with IBS, with up to 80% of them reporting to have at least one red flag, explaining why colonoscopy with or without colonic biopsies is often performed. In the United States, it is estimated that 24% of colonoscopies are related to IBS.[5] In the UK and Italy, colonoscopy was reported in 55% and 50% of patients with IBS, respectively.[6] In France, 23% of participants in a nationwide online health survey[7] and 87% of members of an IBS patient association had at least one colonoscopy in their workup.[1] Furthermore, when Crohn's disease is suspected but ileocaecal intubation is not possible, or the ileum is only seen over a few centimeters, other tests such as MR enterography and/or small bowel capsule endoscopy are sometimes performed after a normal colonoscopy.

A new panenteric capsule, the PillCam™ Crohn's Capsule (pancapsule, Medtronic France, Paris, France), now makes it possible to non-invasively examine both the small bowel and colon in a single procedure. This capsule could be an alternative examination for patients with suspected IBS in whom an organic digestive disease needs to be ruled out. The

feasibility and value of the pancapsule for this purpose remain to be determined. Therefore, the aim of this prospective study was to evaluate the feasibility of a strategy based on the pancapsule in combination with standard recommended biological tests to exclude a putative digestive disease diagnosis in patients younger than 50 years with chronic abdominal symptoms suggestive of IBS, as an alternative to the classical approach based on colonoscopy and standard recommended biological tests. The secondary objectives of this study were (i) to assess patient acceptability of the pancapsule compared to colonoscopy in this setting and (ii) to assess the added value of biological tests, including fecal calprotectin, for diagnostic yield.

Methods

Study Design

This feasibility study was designed as a monocentric, self-controlled (each patient served as their own control), prospective study and was conducted from November 2018 to July 2022. The Ethics Committee (CPP Anger Ouest II) approved the study (No 2018/14), and the protocol was registered on ClinicalTrials.gov (NCT03806959). This study was conducted in accordance with the principles of the Declaration of Helsinki. The main milestones of the study were the pre-selection of patients for assessment of inclusion and non-inclusion criteria and provision of information about the study at visit 0 (D-30 to D-1); inclusion after re-assessment of inclusion and non-inclusion criteria with the signature of the informed consent form, measurement of anthropometric parameters, report of drug intake with standardized clinical assessment and prescription for biological analysis at visit 1 (D 0); pancapsule was administered at visit 2 (D 16 to D 30); colonoscopy with upper endoscopy under general anesthesia were performed at visit 3 (D 17 to D 45), and follow-up with the recording of procedure assessment was performed at visit 4 (up to D 90).

Inclusion and Exclusion Criteria

All adult patients aged 18–50 years were eligible for inclusion if they had symptoms consistent with IBS for more than 6 months, fulfilled the Rome IV criteria, had no known medical conditions that could explain the symptoms, had not had a colonoscopy in the previous 10 years, and were considered by their physician to require a colonoscopy.

Exclusion criteria included swallowing disorders, dysphagia, Zenker's diverticulum, clinical suspicion of digestive stenosis, history of digestive surgery other than an appendectomy, altered general condition and/or dehydration, any uncontrolled chronic disease including uncontrolled cardiac disease (myocardial infarction within the past 6 months, decompensated coronary artery disease, congestive heart failure class III and above according to NYHA classification, ventricular tachycardia, ventricular fibrillation, severe heart block), patients with a pacemaker or other implantable medical electronic device, allergy to polyethylene glycol, oral iron intake in the four days prior to the examinations, pregnant or breastfeeding women, women of childbearing age without an effective method of contraception, women of childbearing age without a pregnancy test. Patients who could not be followed up for psychological or geographical reasons, those under curatorship, and those participating in another clinical trial were not considered for inclusion.

Symptom Evaluation

Digestive symptoms were recorded at enrolment. The intestinal transit was assessed using the Bristol Scale questionnaire. Symptom severity was assessed using the validated gastrointestinal questionnaire IBS-SSS.[8] This five-item questionnaire measures the frequency and intensity of abdominal pain, severity of abdominal distension, dissatisfaction with bowel habits, and interference of IBS with daily life, scoring from 0 to 500. The usual cut-offs of the IBS-SSS scores were used to assess the severity of IBS: < 175 for mild IBS, 175–300 for moderate IBS, and > 300 for severe IBS. The Hospital Anxiety and Depression (HAD) scale, which is widely used to measure general psychological morbidity, and a specific assessment of the quality of life (IBS-QoL) were also used (score 0 to 100, which is the best possible quality of life).

Biological Tests

A panel of routine biological tests, including complete blood count, C-reactive protein, thyroid-stimulating hormone, and anti-transglutaminase antibodies, was performed as recommended for usual care in patients with suspected IBS. Fecal calprotectin levels were also measured.

Pancapsule and "Classical" Endoscopy

Capsule Procedure

Preparation consisted of a low-fiber diet from day - 3 to day - 0, calcic sennoside 20 mg on day - 1, and a sequence of 2 L polyethylene glycol in the evening and 30 mL sodium dihydrogen phosphate/sodium hydrogen phosphate 24.4 g/10.8 g solution in the morning (booster 1), then 1 L water, 25 mL sodium dihydrogen phosphate/sodium hydrogen phosphate 24.4 g/10.8 g solution (booster 2), and 0.5 L water on day - 0. Panenteric capsule exploration was performed using the pancapsule system with Medtronic v9 software. All videos were downloaded to a central storage unit. Capsule readings were performed by a single expert with more than 2000 previous capsule readings (BB) prior to endoscopies. Since the pancapsule is not designed to examine the upper digestive tract, the detection of lesions in the upper digestive tract is only reported for descriptive goals but without comparison to classic upper endoscopy with biopsies.

Colonoscopy with Upper Endoscopy

All patients included in this protocol underwent colonoscopy and upper endoscopy according to current practice using high-definition endoscopes under anesthesia. Preparation for colonoscopy consisted of a low-fiber diet from day 3 to day 0 and a 2L split-dose polyethylene glycol with a simethicone regimen on the evening of day 0. All examinations were performed by a single attending physician (GA), blinded to the pancapsule results. The pancapsule results were unblinded at the end of the endoscopies to avoid non-detection of clinically significant lesions. These examinations were recorded for re-analysis as needed. Biopsies were taken from the stomach, duodenum, and colon. Biopsies were analyzed by an expert in gastrointestinal pathology (NC).

Endpoints

The main endpoint was the difference in detecting digestive lesions between a strategy based on the pancapsule or colonoscopy. The secondary endpoints were the assessment of patient acceptability of the pancapsule compared to colonoscopy, and the added value of biological tests to the diagnostic yield. Discrepancies between the panenteric capsule and classical endoscopy findings were re-analyzed during a second reading of the studies to reach a consensus diagnosis. The consensus diagnosis was then used to show the abnormalities characterized by the pancapsule-based strategy versus the classical strategy based on colonoscopy and upper endoscopy with biopsy. Safety was assessed at each visit and the final visit. Only events that occurred between enrolment and the last visit were reported. Patient preference was evaluated using a simple structured questionnaire administered after both procedures had been completed.

Statistical Analysis

Percentages and means for continuous data (95% confidence interval using t distribution) are presented. In this feasibility study, the distributions of variables were not compared between those with positive and negative endoscopy findings or with any other parameter.

Results

Patients' Characteristics

Forty-two consecutive subjects were screened for eligibility at the pre-selection visit, and thirty-three were enrolled with the signature of informed consent (Figure 1). Four enrolled patients did not have a subsequent procedure (3 were lost to follow-up and one had an early pregnancy). Two patients had only the pancapsule as they did not present for their scheduled upper endoscopy and colonoscopy. The mean age of the patients was 35.1 ± 9.1 years (Table 1). Body mass index (BMI) was 25.4 ± 5.7 $kg.m^{-2}$, with 6 patients having a BMI >30 (20.7%) and none having a BMI >35 (Table 1). Only one patient had a previous normal colonoscopy more than 10 years before inclusion, and all others had no previous

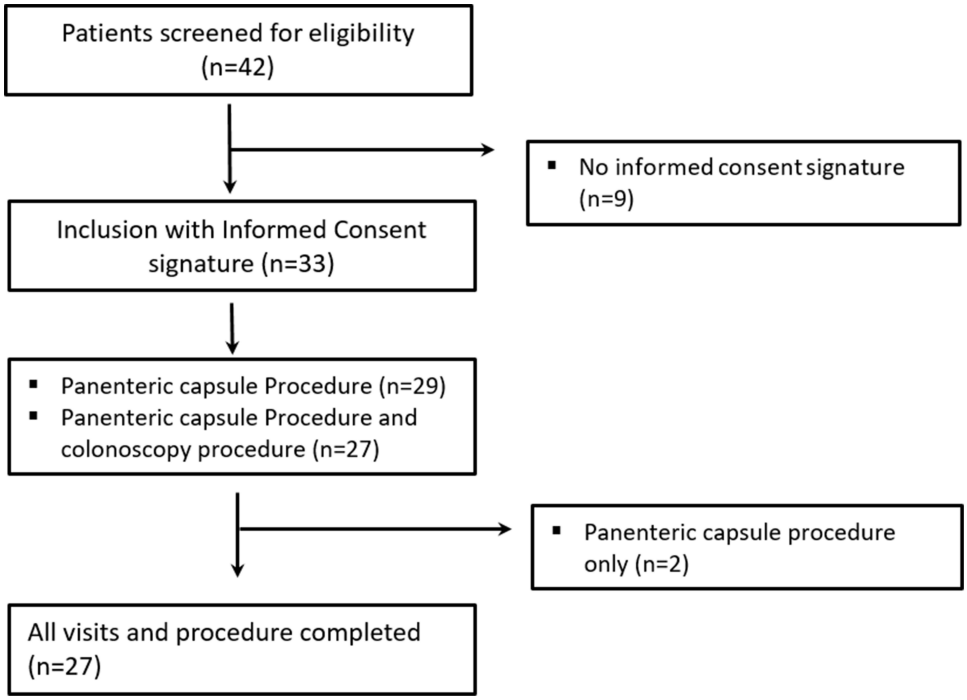


Figure 1 Flow chart of the study.

endoscopic examination. At inclusion, 17 patients (51%) had suspected IBS with predominant diarrhea or mixed phenotypes according to the current Rome IV criteria, 8 (24%) had suspected IBS with predominant constipation phenotype, and 8 patients (24%) had an unclassified subtype (Table 2). Most patients had a stool with a Bristol score of 6 or 7 (Table 2). Of the 27 patients with severity scores, 18 had mild to moderate IBS, and 9 had severe IBS. The HAD scale at enrolment was 16.0 ± 7.0 points (Table 2). Complete blood count, C-reactive protein, thyroid-stimulating hormone, and anti-transglutaminase antibodies were obtained in 28 of the 29 explored patients (Table 3). No biological abnormalities were observed in 23 of these 28 patients, and mild abnormalities were observed in 5 patients, including minimal anemia in 2 cases, transient mild leukocytosis in 1 case, and mild CRP elevation in 3 cases, including one of these 3 cases with also minimal anemia and mild elevation of fecal calprotectin levels (Table 3).

Table 1 Characteristics of the Included and Explored Patients

Item	Included n = 33	Explored n = 29
Gender: M/F	17/16	14/15
Age (Years, mean ± SD)	35.3 ± 8.7	35.1 ± 9.1
Height (Meter, mean ± SD)	1.72 ± 0.1	1.72 ± 0.1
Weight (Kg, mean ± SD)	75.1 ± 16.8	74.8 ± 16.3
BMI (Kg/m^2, mean ± SD)	25.1 ± 5.8	25.4 ± 5.7

Abbreviations: BMI, body mass index; F, female; M, male; SD, standard deviation.

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Table 2 IBS Subtypes and Characteristics of the Included and Explored Patients

Item	Included n = 33	Explored n = 29
IBS-D, n (%)	14 (42.4)	11 (38.0)
IBS-C, n (%)	8 (24.2)	7 (24.1)
IBS-M, n (%)	3 (9.0)	3 (10.3)
IBS-U, n (%)	8 (24.2)	8 (27.6)
IBS-SSS score (Mean ± SD)	242 ± 107	233 ± 114
HADS score (Mean ± SD)	16.0 ± 7.0	15.6 ± 6.4
Bristol scale (n=27)	1 (n=3), 2 (n=5), 3 (n=1), 4 (n=5), 5 (n=6), 6 (n=7), 7 (n=0)	

Abbreviations: HAD, Hospital Anxiety and Depression Scale; IBS, irritable bowel syndrome (C, constipation-predominant; D, diarrhea-predominant; M, mixed type; U, unspecified); IBS-SSS, IBS Severity Scoring System; n, number; SD, standard deviation.

Table 3 Biological Assessment at Inclusion (n=28)

Item	Unit	Reference Values	Mean ± SD	Abnormal Values (n, %)	Abnormal Values Details
Hemoglobin	g/dL	12.0–16.0	14.1 ± 1.5	n=2 (7%)	11.8, 11.3
Leukocytes	/mm^3	4000–10,000	6360 ± 2225	n=1 (3%)	15,300
Neutrophils	/mm^3	1800–7700	3591 ± 2192	n=1 (3%)	12,220
Eosinophils	/mm^3	40–400	146 ± 87	–	–
C-reactive protein	mg/L	< 5.0	3.9 ± 7.4	n=3 (10%)	39.0, 11.6 and 7.5
TSH	µUI/mL	0.27–4.20	1.6 ± 0.9	–	–
Anti-transglutaminase IgA	U/mL	< 17	2.5 ± 1.6	–	–
Fecal calprotectin	mg/g	< 50	24.9 ± 27.2	n=1 (3%)	107

Abbreviations: IgA, Immunoglobulin A; TSH, Thyroid-Stimulating Hormone.

Detected Lesions and Procedure Acceptability

Pancapsule

The pancapsule was performed in 29 patients. In one patient, the recorder was changed on the same day due to a technical problem, without affecting the examination. The capsule was passed in 25 cases (86%) and remained in the rectum in 3 cases. One procedure was incomplete as the capsule only reached the transverse colon and was removed during a colonoscopy the following day. Small bowel preparation was excellent or good in all cases. Colon preparation was excellent in 12 cases, good in 15 cases, fair in one case, and poor in one case.

The pancapsule showed diminutive angiodysplasia in 4 patients (all type 1a or 1b according to the Yano-Yamamoto classification; terminal ileum, n=2; proximal colon, n=1; and distal colon, n=1), diminutive or small polyps in 4 patients including one in the esophagus (3 mm), one in the duodenum (2 mm), and 4 in the distal colon (3 to 7 mm), diverticula in 7 patients, mainly in the distal colon, and mild colonic or rectal erythema in 2 patients (Table 4 and Supplementary Table). These lesions were unrelated to digestive symptoms and had little or no clinical interest.

Colonoscopy & Upper Endoscopy

Colonoscopy was performed on 27 patients. Bowel preparation was excellent to good, with a Boston score > 6 in 24 patients (89%; Boston score of 7 in 3 patients, 8 in 14 patients, and 9 in 7 patients). Two patients had a Boston score of 6

Table 4 Lesions Findings After Consensus Reading

Localization	Lesion*	Pancapsule	Upper Endoscopy & Colonoscopy	Discrepancy
Esophagus	Gastric ectopia	–	1	NE
	Barrett's esophagus	–	5	NE
Stomach	Mild fundic atrophy	–	2	NE
	Gastritis	–	10	NE
	Ulcer/ulceration	–	2	NE
Duodenum	Duodenitis	0	2	2
	Polyp	1	0	1
Small bowel	Angiodysplasia	2	–	2
	Lymphangiectasia	1	–	1
Colon/Rectum	Angiodysplasia	3	0	3
	Erythema	2	2	1
	Diverticula	12	5	15
	Polyp	4	4	3

Notes: *One patient could have more than one lesion. As the pancapsule is not designed to investigate the upper gastrointestinal tract, capsule detection of upper tract lesions was not mentioned in this Table (for more detailed results, see text and Supplementary Table).
Abbreviation: NE, Not evaluable.

and one patient had an incomplete colonoscopy due to solid stool in the right colon with a Boston score of 3. Ileal intubation was performed in 21 patients (81%). No ileal lesion was observed. Colonoscopy showed 4 diminutive polyps in 4 patients (all 2–3 mm; one in the right colon, one in the transverse colon, and two in the sigmoid colon). All polyps were resected and consisted of normal mucosa (n=1), hyperplastic polyp (n=1), and low-grade dysplastic tubular adenoma (n=2). Small multiple diverticula (n=5) were noted in the proximal colon in one patient. Mild colonic and rectal erythema were reported in one patient, respectively (Table 4). Colonic biopsies did not reveal microscopic colitis. All lesions characterized by colonoscopy were considered to be unrelated to digestive symptoms and of little or no clinical interest. Discrepancies between the pancapsule and colonoscopy findings are shown in Table 4.

Upper endoscopy was performed in 27 patients and showed an aspect of "ultra-short" (n=4, all C0 and < 5 mm) or short Barrett's esophagus (n=1, C0-M1), mild fundus atrophy in 2 patients, mild gastritis in 10 patients, gastric ulcer in 2 patients (8 and 10 mm, Forrest III) and duodenitis in 2 patients (Table 4). Gastric fundus and antral biopsies, as well as duodenal biopsies, were performed in 26 patients. Twelve patients had *H. pylori* infection (46%). A MALT lymphoma (lymphoepithelial CD20+ CD5+ features with low-intensity Kappa B clonal rearrangement) with no endoscopically reported lesion was diagnosed in one patient on only one systematic gastric biopsy. This MALT lymphoma was not further characterized after successful *H. pylori* eradication. Two patients had mild duodenal intraepithelial lymphocytosis (21 and 20%).

The 25 small bowel and colonic lesions identified in 15 patients by the pancapsule and the 11 colonic lesions identified in 7 patients by colonoscopy were considered to be unrelated to digestive symptoms.

Acceptability

Acceptability was evaluated in 27 patients. All patients considered capsule ingestion easy, except in 2 cases in which ingestion was evaluated as medium. Capsule preparation was reported to be associated with mild abdominal discomfort in all patients, except in 4 cases with more marked discomfort, even associated with mild vomiting in 3 cases. All patients declared that they would agree to redo the capsule procedure. On the contrary, two patients declared that they would disagree with redoing the colonoscopy, and 3 others that they would have to reconsider it. Preference for a capsule procedure was expressed in all cases.

Discussion

In patients suspected of IBS diagnosis, the value of the frequently performed endoscopic workup is to rule out the possibility of another undiagnosed digestive disease. In this feasibility study performed in patients with suspicion of IBS under 50 years old, without prior recent endoscopic exploration, both the pancapsule and "classical" upper and lower endoscopic explorations were frequently abnormal (55 and 74% of explorations with at least one abnormality). In the pancapsule strategy, the 25 lesions of the small bowel or colon reported in 15 patients were of little or no clinical interest, not requiring specific treatment or suggesting an alternative diagnosis that could explain the symptoms.

These preliminary data are of particular interest since no previous study evaluating the role of pancapsule in a young population with suspicion of IBS diagnosis is available. The value of small bowel capsule endoscopy in patients with undiagnosed chronic abdominal pain or chronic diarrhea is also poorly studied and still debated. The reported diagnostic yield in available studies, including selected patients with undiagnosed chronic abdominal pain, varies from 2 to 44% of explored patients with a pooled diagnostic yield of 21% in a total of 1520 patients explored in 21 studies.[9,10] In these studies, clinical alarm signs such as weight loss and/or laboratory signs of inflammation (leukocytosis, increased CRP levels) are associated with a higher diagnostic yield with more frequent clinical impact. Fecal calprotectin was normal in almost all patients except only one who had a mild increase, without finding a specific lesion that could explain this abnormality. The added value of calprotectin in this context remains to be explored but is expected to be limited.

This feasibility study suggests that the pancapsule could have a good negative predictive value for both small bowel and colonic clinically relevant conditions in young patients suspected of IBS and compares favorably with colonoscopy. Since upper endoscopy identified 3 clinically significant lesions missed by the pancapsule, the possibility of better exploring the stomach with magnetically guided capsules should also be evaluated in this context. The acceptability of the pancapsule was very good, and this procedure was preferred to colonoscopy in this population, which has similar characteristics to those of IBS populations described in other studies.

This study demonstrates the feasibility of using the panenteric capsule combined with standard biological tests to exclude GI diseases in young adults with symptoms suggestive of IBS, as an alternative to an approach based on colonoscopy. All patients preferred the panenteric capsule procedure over classical endoscopic methods, indicating higher acceptability. The study found that lesions identified by both the capsule and colonoscopy were unrelated to digestive symptoms and were of little or no clinical interest, suggesting that panenteric capsule endoscopy might be a sufficient initial investigation in patients with suspected IBS. The diagnosis of IBS was not altered in any of the patients explored, supporting the potential of the panenteric capsule as a first-line examination tool for excluding significant GI diseases in young adults with chronic abdominal symptoms with an indication to perform a colonoscopy. Studies with larger sample sizes, patients over 50, and non-invasive upper GI evaluations are needed before recommending its clinical use; the cost-effectiveness of the pancapsule compared to colonoscopy and the role for each subtype should also be investigated.

In conclusion, the diagnosis of IBS was not questioned in any of the patients explored. These preliminary results demonstrate the feasibility of a strategy based on the use of a panenteric capsule, in combination with standard biological tests, to exclude organic gastrointestinal disease in young adult patients presenting with chronic abdominal symptoms suggestive of IBS.

Data Sharing Statement

The authors do not intend to share any individual participant data or related study documents.

Ethical Statement

The Angers Ethics Committee has approved this prospective study (CPP Ouest II, No 2018/14). This study was conducted in accordance with the principles of the Declaration of Helsinki.

Registration

The study protocol was registered on ClinicalTrials.gov (NCT03806959) and received the ANSM identifier number 2017-A03229-44.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Dr Fabien Wuestenberghs reports personal fees from Biocodex France, Menarini Belgium, Biocodex Belgium, and Grünenthal; non-financial support from Viatris, outside the submitted work. Professor Jean-Marc Sabaté reports personal fees from RECKITT, KYOWA KIRIN, DEVINTEC, BIOCODEX, NOVOZYMES, and MENARINI, outside the submitted work. All authors declare that they have no other conflicts of interest in this work.

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