Comparing diagnostic yield of a novel pan-enteric video capsule endoscope with ileocolonoscopy in patients with active Crohn's disease: a feasibility study

Jonathan A. Leighton, MD,[1] Debra J. Helper, MD,[2] Ian M. Gralnek, MD, MSHS,[3] Iris Dotan, MD,[4] Ignacio Fernandez-Urien, MD,[5] Adi Lahat, MD,[6] Pramod Malik, MD,[7] Gerard E. Mullin, MD,[8] Bruno Rosa, MD[9]

Scottsdale, Arizona; Indianapolis, Indiana; Baltimore, Maryland, USA; Afula, Tel Aviv, Israel; Navarra, Spain; Guimarães, Portugal

Background and Aims: Crohn's disease (CD) is typically diagnosed with ileocolonoscopy (IC); however, when inflammation is localized solely in the small bowel, visualization of the entire small-bowel mucosa can be challenging. The aim of this study was to compare the diagnostic yield of a pan-enteric video capsule endoscope (small-bowel colon [SBC] capsule) versus IC in patients with active CD.

Methods: This was a prospective, multicenter study. Patients with known active CD and proven bowel luminal patency underwent a standardized colon cleansing protocol followed by ingestion of the capsule. After passage of the capsule, IC was performed and recorded. Lesions indicative of active CD were assessed.

Results: One hundred fourteen subjects were screened; 66 subjects completed both endoscopic procedures. The per-subject diagnostic yield rate for active CD lesions was 83.3% for SBC and 69.7% for IC (yield difference, 13.6%; 95% confidence interval [CI], 2.6%-24.7%); 65% of subjects had active CD lesions identified by both modalities. Of the 12 subjects who were positive for active CD by SBC only, 5 subjects were found to have active CD lesions in the terminal ileum. Three subjects were positive for active CD by IC only. Three hundred fifty-five classifying bowel segments were analyzed; the per-segment diagnostic yield rate was 40.6% for SBC and 32.7% for IC (yield difference 7.9%; 95% CI, 3.3%-12.4%).

Conclusion: This preliminary study shows that the diagnostic yields for SBC might be higher than IC; however, the magnitude of difference between the two is difficult to estimate. Further study is needed to confirm these findings. (Gastrointest Endosc 2017;85:196-205.)

Crohn's disease (CD) is an idiopathic, relapsing, and remitting inflammatory condition that can involve any portion of the luminal GI tract.[1] Symptoms may be due to fibrostenotic strictures, luminal or transmural inflammation complicated by fistulizing disease, abscess, or extraintestinal manifestations. Most commonly, CD involves the terminal ileum (TI) and proximal colon.[2] Historically, direct endoscopic examination of the luminal

Abbreviations: AE, adverse event; CD, Crohn's disease; CE, capsule endoscopy; CI, confidence interval; ESR, erythrocyte sedimentation rate; IC, ileocolonoscopy; MRI, magnetic resonance imaging; PEG, polyethylene glycol; SAE, serious adverse event; SBC, small-bowel colon; TI, terminal ileum.

DISCLOSURE: *The following authors disclosed financial relationships relevant to this publication: J.A. Leighton, I.M. Gralnek, D.J. Helper, I. Fernandez-Urien, A. Lahat, M. Pramod, G.E. Mullin, and B. Rosa: Medtronic; I. Dotan: Medtronic, The Leona M. and Harry B. Helmsley Charitable Trust, Janssen, Abbvie, Takeda, Genentech, Pfizer, Ferring, Falk Pharma, Rafa, Protalix, and MSD.*

Copyright © 2017 by the American Society for Gastrointestinal Endoscopy
0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2016.09.009

Received September 12, 2016. Accepted September 12, 2016.

Current affiliations: Mayo Clinic Arizona, Scottsdale, Arizona, USA (1), Indiana University School of Medicine, Indianapolis, Indiana, USA (2), Institute of Gastroenterology and Liver Diseases, Ha'Emek Medical Center, Afula, Israel (3); IBD Center, Department of Gastroenterology and Liver Diseases, Tel Aviv Sourasky Medical Center, and the Sackler Faculty of Medicine, Tel Aviv, Israel (4); Hospital de Navarra, Navarra, Spain (5); Department of Gastroenterology, Sheba Medical Center and Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel (6), Gastrointestinal and Liver Specialists of Tidewater, Suffolk, Virginia, USA (7), The Johns Hopkins University School of Medicine, Baltimore, Maryland, USA (8), Gastroenterology Department, Centro Hospitalar do Alto Ave, Guimarães, Portugal (9).

Reprint requests: Jonathan A. Leighton, MD, Mayo Clinic Arizona, 13400 E. Shea Blvd., Scottsdale, AZ 85259.

If you would like to chat with an author of this article, please contact Dr Leighton at Leighton.Jonathan@mayo.edu.

GI tract has been limited to the colon and TI via colonoscopy, and the esophagus, stomach, and duodenum via EGD. Indirect radiographic imaging is most often used to examine the remainder of the small bowel. Since the development of video capsule endoscopy (CE), direct endoscopic examination of the entire small-bowel mucosa is possible.[3-5] However, complete examination of the GI tract still requires a combination of procedures.

The small-bowel colon (SBC) capsule (PillCam Crohn's [Medtronic, formerly known as Given Imaging, Yoqneam, Israel]) was designed to image the small bowel and colon. The capsule was developed to provide clinical and health outcome benefits to patients and physicians by offering a single test, replacing multiple diagnostic procedures in CD patient management. The SBC capsule is a two-headed video capsule, with a field of view of 172 degrees in each head, and a frame rate up to 35 frames per second that adapts to the speed of capsule transit through the bowel (Supplementary Fig. 1, available online at www.giejournal.org). The SBC capsule is similar to the second-generation colon capsule (PillCam COLON 2, Medtronic, formerly known as Given Imaging, Yoqneam, Israel) in all its hardware components, but differs in its operation mode, designed to provide complete coverage of the small bowel in addition to the colon. The video compilation for the SBC system has been optimized for efficient visualization of lesions indicative of inflammatory bowel disease.

The aim of this prospective feasibility study was to assess the efficacy and safety of the SBC capsule in subjects with signs and symptoms of active CD by evaluating the (1) per-subject and per-segment diagnostic yield of the SBC capsule within the TI and colon as compared with that of ileocolonoscopy (IC) alone; (2) per-subject diagnostic yield of the SBC capsule within the proximal small bowel (this was a priori defined as anywhere in the small bowel proximal to the TI); and (3) safety of the SBC procedure.

METHODS

Study design

This prospective, multicenter study evaluated the SBC CE system for visualization of lesions that might indicate active CD in the small bowel and colon. Results of SBC were compared with IC in subjects with active, symptomatic CD. Subjects enrolled into the study were from 6 study sites in the United States and 3 study sites in Israel. This study was conducted according to Good Clinical Practice guidelines and the Declaration of Helsinki. All local regulations were adhered to, and human subjects committee approval was obtained from each study site. This trial was registered at ClinicalTrials.gov (number NCT01631435).

Study participants

Eligible participants gave informed consent before screening. Subjects were then screened on the basis of study-defined inclusion and exclusion criteria (Table 1). It was also required to prove patency of the GI tract within the preceding 90 days of the capsule procedure. Subjects who met all inclusion criteria, but none of the exclusion criteria, were enrolled into the study.

Materials

The PillCam Platform (Medtronic, formerly known as Given Imaging, Yoqneam, Israel) was provided by the study sponsor and includes (1) SBC capsule, (2) data recorder (DR3), (3) RAPID Real-Time software, and (4) Given Workstation. A purgative sulfate-free polyethylene glycol electrolyte lavage solution and Suprep Bowel Prep Kit (Braintree Laboratories, Braintree, Mass) preparation were used. Colon preparations for the IC procedure were those routinely used at the study site where the procedure was performed.

Procedure

After informed consent was obtained, stool and blood tests were sent to the local laboratory of the study site to verify eligibility. A complete history and physical examination were performed, and concomitant medications were recorded. Women of childbearing potential underwent urine pregnancy testing. Subjects who had not had a study to prove patency of the luminal GI tract in the previous 90 days or who, at the investigator's discretion, required further proof of GI tract luminal patency ingested a patency capsule. Subjects documented passage of the patency capsule either by collecting it and presenting it to the study coordinator or by taking a digital picture of it after passage. If it was not reliably passed, the subject was evaluated with a patency scanner. If a patency scanner was not available, fluoroscopy or radiography was used to detect a retained patency capsule. If the patency capsule was found to be retained, the subject was excluded from the study. If the patency capsule was believed to be in the colon, CT could be performed to prove its location within the colon, and these subjects were allowed to continue in the study.

All subjects enrolled into the study were required to follow a bowel preparation regimen beginning the day before the capsule procedure (Table 2). The SBC capsule procedure was determined to be completed when the capsule was naturally excreted, when the DR3 alerted "end of procedure," or 10 hours after capsule ingestion. After completion of the SBC capsule procedure, the raw data and RAPID video were downloaded from the DR3 to the Given Workstation.

After completion of the capsule procedure or on the following day (while maintaining a clear liquid diet), IC was performed and recorded on VCR or DVD. The colonoscope withdrawal time was to be no less than 6 minutes. The quality of the preparation in each bowel segment (TI, cecum, ascending colon, transverse colon, descending/sigmoid colon, and rectum) was recorded by the colonoscopist using the Leighton and Rex Scale.[6] In addition, the colonoscopist

Download English Version:

https://daneshyari.com/en/article/5659180

Download Persian Version:

https://daneshyari.com/article/5659180

Daneshyari.com