Wireless Capsule Endoscopy

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The small bowel is the most difficult part of the bowel to examine owing to the distance from mouth to anus. Conventional endoscopic techniques for examining the small bowel are limited by the length of the small intestine (3.5–7.0 m) [1] and by its multiple complex looped configurations. The current methods for imaging the small bowel include, primarily, barium X-rays and enteroscopy. However, for a wide variety of specific lesions the diagnostic value of these tests is low.

A barium small bowel series, the most commonly used investigation, is unable to demonstrate flat lesions such as angiodysplasias, one of the most common pathologic lesions [2,3]. In addition, the small bowel series has a low sensitivity for raised lesions [4]. Barium X-rays of the small bowel are currently the primary radiographic means of diagnosing a small bowel neoplasm and the optimal way to locate small bowel lesions, but its sensitivity is only 30–44%. Diagnostic sensitivity for small bowel neoplasms can be increased by enteroclysis, which is extremely inconvenient for the patient and must be done in a hospital setting by an expert. Another serious drawback of radiologic studies is the damage rendered by the irradiation. Computerized tomography of the abdomen is sometimes helpful in diagnosing and localizing small bowel abnormalities, but it cannot determine small intraluminal or mucosal lesions.

Enteroscopy is a method of performing direct visual inspection of the small bowel mucosa beyond the reach of standard upper endoscopes. Push-enteroscopy requires a skilled endoscopist. The procedure requires between 15 and 45 minutes; it is uncomfortable and often painful, usually requiring sedation and analgesia; and there is a danger of perforation [5]. In addition, the instrument can only examine between 80 and 120 cm beyond the ligament of Trietz [6]. Occasional complications may occur, usually relating to the use of an overtube to facilitate deep intubation of the small bowel. Improved instrument design and therapeutic capability has led to an increasing use of push-enteroscopy. Sonde endoscopy, in theory, has the potential to examine the entire small bowel. In Sonde enteroscopy a long scope is inserted trans-nasally into the stomach and pushed through the pylorus with a gastroscope passed through the mouth [7]. It is carried by peristalsis, which propels a balloon inflated at the tip. Sonde enteroscopy requires a long examination time (6–8 hours), is extremely uncomfortable and often painful, and also carries the danger of perforation. For these reasons it is not widely performed [8]. Another approach to small bowel imaging is to examine the entire small bowel by intraoperative enteroscopy.

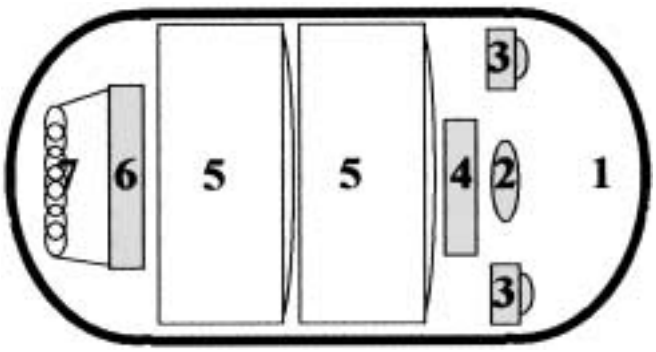
It is generally accepted that the current visualization and imaging methods available to the gastroenterologist for diagnosing small bowel diseases and disorders are unsatisfactory [5]. The need for endoscopic examination of the small bowel is now well established, particularly for obscure gastrointestinal bleeding [6,9,10], but also for the diagnosis and screening of small bowel tumors, polyposis syndromes [11] and inflammatory diseases of the small bowel [12].

In patients presenting with obscure gastrointestinal bleeding in the presence of a normal upper GI endoscopy and colonoscopy, a small bowel source can be identified in up to 40% of the cases with push or Sonde enteroscopy. In one series Sonde enteroscopy was able to detect only 26% of the lesions in the distal portion of the intestine [13]. Therefore, there is a clear need for a solution that will be relatively comfortable for the patient, easy to use by the gastroenterologist, inexpensive, and provide a reasonable level of visual imaging for the detection of small bowel abnormalities.

A new system designed to aid the gastroenterologist in diagnosing small bowel diseases is the Given Diagnostic Imaging System (M2A Capsule).

The Given M2A capsule [Figure 1] [14,15] is composed of three main subsystems: ingestible capsule, data recorder, and workstation equipped with proprietary image-processing software. The capsule – the disposable, ingestible, *M2AImaging Capsule* [Figure 1] – acquires video images during natural propulsion through the digestive system. The capsule transmits the acquired images via a digital RF communication channel to the recorder unit located outside the body. The data recorder is an external receiving/recording unit that receives the data transmitted by the ingestible capsule. The portable data recorder consists of a sensor array

GI = gastrointestinal



Key: 1. Optical dome. 2. Lens. 3. Illuminating LEDs
4. CMOS imager 5. Battery 6. ASIC Transmitter 7. Antenna

Figure 1. Schematic diagram of the M2A capsule

attached to the abdomen, and a receiver that measures signal strength at each sensor. The receiver selects the strongest signal from which it receives the video data. The recorder also contains memory media for accumulation of the signal strength and video data during the examination. Upon completion of the examination, the physician transfers the accumulated data in the recorder to the workstation for interpretation. The data transfer is performed via high capacity digital link. The workstation, equipped with RAPID advanced image-processing software, is a modified standard personal computer that is intended for off-line storage, interpretation and analysis of the acquired data, and generating reports.

Clinical trials are presently being performed to evaluate the safety and efficacy of the system as a tool in the detection of small bowel diseases. Preliminary results show that the Given M2A capsule provides good visualization from mouth to colon and successfully images pathologic features of the small bowel [Figures 2 and 3]. All the patients participating in the ongoing clinical study found the capsule easy to ingest, painless, and preferable to conventional endoscopy. In these clinical trials, which used the Given System, push-enteroscopy, or surgical techniques in 20 patients, the Given System detected physical abnormalities in 12 (60%), while push-enteroscopy detected physical abnormalities in 7 (35%). In total, 14 lesions were detected in 13 of the 20 patients. The Given System detected 12 of the 14 lesions (86%), while push-enteroscopy detected 7 of 14 lesions (50%). In the clinical trial supporting our FDA application and the two feasibility trials described above, a total of 55 patients ingested one M2A capsule each. In these combined trials, the Given System either confirmed or expanded the suspected diagnosis in 34 of 55 patients (62%) [16,17].

Indications for the capsule include small bowel disease, occult bleeding (iron deficiency anemia), suspected Crohn's disease, unexplained diarrhea, and malabsorption. Among the contraindications are pediatric patients, small bowel obstruction, strictures of the bowel, dysphagia, gastroparesis, and uncooperative patients.

Conclusion

The modalities of small bowel imaging include barium X-rays, push-enteroscopy, and wireless capsule endoscopy. Barium X-ray offers a low diagnostic yield, while push-enteroscopy, which has a higher yield, is an uncomfortable procedure and requires expertise by the endoscopist. Since January 2001, over 230 patients have ingested the M2A capsule as part of a program of ongoing clinical trials in over 20 different sites in the United States, Europe, Israel and Australia. According to preliminary data from ongoing clinical trials in France, Germany and Australia in which the Given System was compared to push-enteroscopy, the Given System detected physical abnormalities in 63 of the 86 patients (73%), while push-

Figure 2. Normal villi of the small bowel

Figure 3. Severe enteritis due to ischemia

enteroscopy detected physical abnormalities in 43 (50%). Wireless capsule endoscopy, a new modality in imaging of the small intestine, has a high diagnostic yield – 60%, and is also a painless procedure. Information gained from capsule endoscopy was helpful in managing the treatment of these patients. The Given M2A Diagnostic System promises to be a valuable tool in the assessment of small bowel disease and is likely to become the first-line procedure in the detection of small bowel disease.

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