M2A™ Capsule Endoscopy

A Breakthrough Diagnostic Tool for Small Intestine Imaging

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It is estimated that 19 million people in the United States may suffer from diseases related to the small intestine, including obscure bleeding, irritable bowel syndrome, Crohns disease, chronic diarrhea, and cancer. Current diagnostic methods, including push enteroscopy and radiology, produce historically low diagnostic yield. Early studies show that the M2A™ Capsule Endoscope effectively visualizes the entire small bowel and demonstrates a 71% superior diagnostic yield when compared to push enteroscopy according to clinical trials reviewed by the FDA. In addition to potentially higher diagnostic yields, it provides a noninvasive diagnostic alternative where none previously existed. The M2A™ Capsule Endoscope received FDA clearance in August 2001 and is currently in use at major medical centers throughout the United States and Europe.

Electronic capsule technology for use in the gastrointestinal tract was initially developed in 1954 to detect temperature, pressure, and pH levels. In August 2001, the FDA cleared a new electronic capsule designed to provide video images of the gastrointestinal tract. The capsule, referred to as the M2A™ Capsule Endoscope, is manufactured by Given Imaging, Ltd. The FDA cleared the device to be used as an adjunctive tool for imaging of small intestine disorders and diseases.

The complete system consists of four components: the RAPID™ Workstation, DataRecorder™ worn on a belt, the Sensor Array™ taped to the abdomen, and the single-use M2A™ Capsule Endoscope. The product is currently for sale in the United States, Canada, Latin America, Europe, Israel, and Australia.

Received October 3, 2001; accepted October 27, 2001.

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The M2A™ Capsule Endoscope measures 11 mm x 26 mm, contains four light emitting diodes (LEDs), a lens, a color camera chip, two batteries, a radio frequency transmitter, and an antenna. The camera uses a complementary metal oxide semiconductor (CMOS) chip, which requires less power than present charged coupled device (CCD) chips found in video endoscopes and digital cameras and can operate at very low levels of light. The capsule is capable of viewing objects having a size of less than 0.1 mm. The transmitter delivers over 50,000 images during the 8-hour procedure. The capsule is sealed in a biocompatible material that is resistant to the digestive fluids. The capsule endoscope is a single-use device propelled by peristalsis through the gastrointestinal tract and is naturally excreted (Figure 1).

Video images are transmitted from the M2A™ Capsule Endoscope using a UHF-band radio telemetry to sensor arrays taped to the patient's abdomen. The sensor arrays are latex-free. The product also received Federal Communications Commission (FCC) clearance for this method of transmission. The images are stored on a portable DataRecorder™ worn around the patient's waist. The capsule enteroscopy procedure is completely ambulatory; the patient does not

FIGURE 1 • Inside the M2A™(Capsule. 1. Optical dome. 2. Lens holder. 3. Lens. 4. Illuminating light emitting diodes (LEDs). 5. Complementary metal oxide semiconductor (CMOS) imager. 6. Battery. 7. Application specific integrated circuit (ASIC) transmitter. 8. Antenna.

need to be confined to a hospital or medical facility during the procedure and is free to continue daily activities.

Imaging the Small Intestine

Enteroscopy involves the visualization of the small intestine using a special endoscope. It is widely accepted that the traditional visualization and imaging methods for diagnosing disorders of the small intestine are inadequate. The traditional methods primarily include barium x-rays and push enteroscopy. The diagnostic value of these tests, particularly for obscure gastrointestinal bleeding, is low. The M2A™ Capsule Endoscope (see Figure 1) has proven to be a safe and effective alternative to traditional imaging methods. The small intestine approximate diagnostic yields for the Given System, push enteroscopy, and radiology are shown in Figure 2.

Prior to the M2A™ Capsule Endoscope, Sonde enteroscopy was the only available nonsurgical method to view inside the entire small bowel, including the ileum. Today, the M2A™ Capsule Endoscope is used by physicians to perform small bowel enteroscopy, including the distal ileum. The new procedure is similar to Sonde enteroscopy in the following steps:

1. The patient is prepared for endoscopy by the nurse or technician.
2. The physician introduces the endoscope and leaves the patient.
3. The endoscope is advanced by peristalsis as it moves to the distal ileum.
4. The patient is not under sedation as the endoscope advances for approximately 8 hours.
5. Approximately 8 hours later, the physician may review the images.
6. Total physician involvement is approximately 1.5 hours.

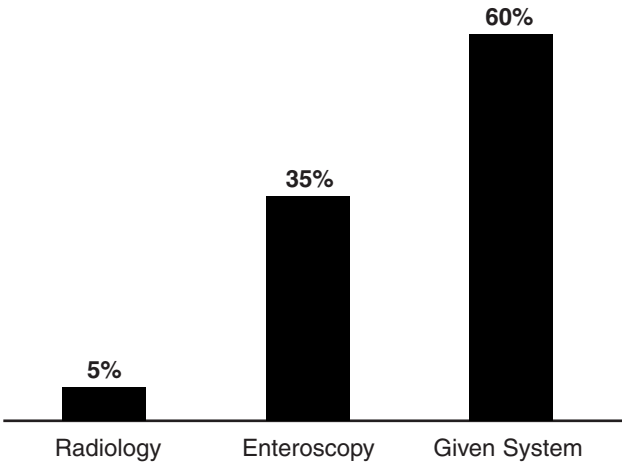

FIGURE 2 • Approximate small intestine diagnostic yield.

In addition to the video imaging capability, the M2A™ Capsule endoscope also provides a standard bolus for measuring esophageal, gastric, and small bowel transit times which may be helpful in diagnosing gastrointestinal motility disorders.

Clinical Results: "The first clinical trial submitted to the FDA"

Dr. Blair Lewis compared capsule enteroscopy to push enteroscopy in 21 patients with obscure GI bleeding and presented his data at the American Society of Gastrointestinal Endoscopy (ASGE) plenary session during Digestive Disease Week 2001. Patients were excluded from the study if there was a history of bowel obstruction, pregnancy, diabetes, or a pacemaker.

Patients underwent capsule enteroscopy after a 12-hour fast. After ingesting the capsule, patients remained NPO for an additional 2 hours, and then were able to drink clear liquids and take medications. After an additional 2 hours, patients could resume their normal diet. The DataRecorder™ with Sensor Array™ was connected to the patient for 8 hours. After the capsule enteroscopy procedure was complete, the patient subsequently underwent push enteroscopy. Two physicians reviewed the capsule images; one was blinded to the clinical background of the patients. The 21 patients included 12 women and 9 men with an average age of 61. Twenty were able to be evaluated.

In this trial, the ease of capsule ingestion was assessed by the investigator as well as by the study patient through a questionnaire. No patient had difficulty ingesting the capsule. Both physicians judged the capsule images as "good to excellent." No discrepancies of the findings were noted.

The M2A™ Capsule enteroscopy was found to be superior to push enteroscopy in the evaluation of obscure bleeding. Capsule endoscopy made a diagnosis in 12/20 (60%) and findings included angiodysplasias, fresh blood, a carcinoid tumor, and an ileal ulcer. Push enteroscopy made a diagnosis in 7/20 (35%). The M2A™ Capsule identified lesions found distally in the small bowel, which were unreachable by push enteroscopy. The overall improvement in diagnostic yield was, therefore, 71% (25 percentage point improvement in diagnostic yield divided by 35% diagnostic yield for enteroscopy) (Figure 3).

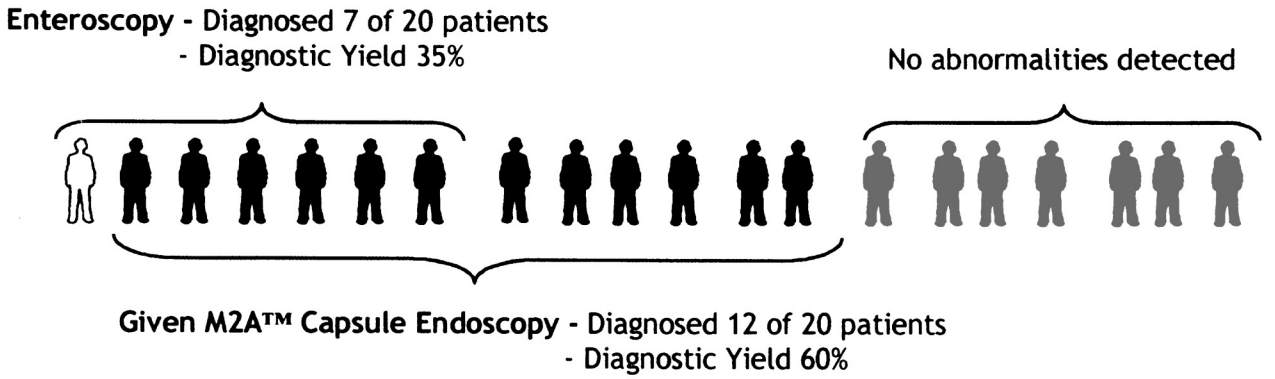

FIGURE 3 • M2A™ clinical trial results reviewed by FDA. 71% superior diagnostic yield.

Clinical trials are being conducted worldwide to investigate the diagnostic efficacy of M2A™ Capsule Endoscopy in a wide range of GI conditions, such as, celiac disease, nonsteroidal anti-inflammatory drug (NSAID) induced mucosal injury, malabsorption, motility conditions, irritable bowel syndrome, and pediatrics. Safety in pregnancy has not been established.

Contraindications

Capsule endoscopy is contraindicated for use in patients with known or suspected gastrointestinal obstruction, strictures, or fistulas based on the clinical picture or preprocedure testing and profile, and patients with cardiac pacemakers or other implanted electro-medical devices.

Patient Preparation

The nurse explains the capsule endoscopy procedure to the patient including why the procedure is being ordered and what to expect during and after the procedure. A significant clinical and patient benefit of the new capsule endoscopy procedure is that the only pre-procedure preparation required of the patient is to fast 8 hours prior to the scheduled procedure time.

The patient preparation at the time of the procedure is very simple. The nurse marks the patient's abdomen using a paper template to indicate the location of the sensors. The nurse then applies the eight-lead Sensor Array™ to the patient's abdomen. The DataRecorder™ and a battery pack are placed inside a belt to be worn around the patient's waist. The Sensory Array™ is connected to the DataRecorder™. The patient is now ready to ingest the M2A™ capsule with a glass of water (Figure 4). Patients can be allowed to leave the medical facility during the 8 hour capsule endoscopy process, though the patient should be advised to refrain from any strenuous activity during this 8-hour procedure period.

Discharge Instructions

The nurse should review the following discharge instructions with the patient before the patient leaves the hospital or medical facility:

1. Remain NPO for 2 additional hours post capsule ingestion; may resume normal diet 4 hours post capsule ingestion.
2. Avoid any source of powerful electromagnetic fields such as MRI while the capsule is inside the body.
3. Contact the physician's office if the patient experiences any nausea, vomiting, abdominal pain, or discomfort.
4. Return to the medical facility after 8 hours or on the day following the procedure with the capsule endoscopy equipment (DataRecorder™, RecorderBelt™, and Sensor Array™).

The nurse should explain to the patient the capsule will be excreted naturally with their bowel movement; usually within 24 to 48 hours after the capsule has been ingested. The patient should not experience any pain or discomfort during the procedure.

Interpreting the Capsule Endoscopy Images

After the 8-hour procedure, the DataRecorder™ is connected to the RAPID™ workstation and the images are downloaded and processed into a color video report for the physician to view and interpret. Standard JPEG files and AVI video clips can be saved from the video report and copied to a disk or e-mailed to a colleague (Figure 5).

FIGURE 4 • The patient ingests the M2A™ Capsule with a full glass of water.

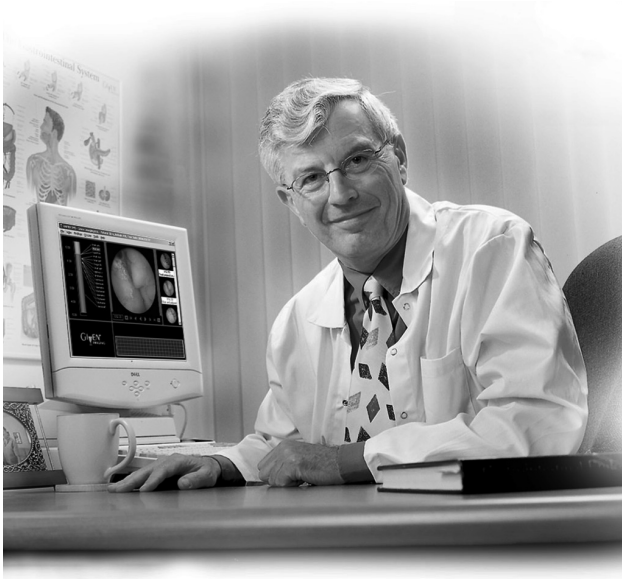

FIGURE 5 • Standard JPEG files and AVI video clips can be saved from the video report and copied to a disk or e-mailed to colleague

Patient Advantages

M2A™ Capsule Endoscopy offers many significant patient advantages over the conventional small intestine imaging and diagnostic modalities. Primary advantages include:

- Performed as an ambulatory and noninvasive procedure
- No need for the patient to be sedated
- No risk of exposure to x-ray or risk of cross-contamination
- Patient can return to their normal activities during the procedure
- Patients are more compliant when choosing among the alternatives

Patient Disadvantages

While the M2A™ Capsule Endoscope provides improved diagnostic capability for the small intestine, it is unable to take a tissue biopsy or perform any therapeutic action. Additionally, the Capsule Endoscope is not an effective tool for imaging the colon.

Conclusions

M2A™ Capsule Endoscopy is a major advance in gastrointestinal diagnostics. Physicians can image the entire small intestine with improved diagnostic yield, while also documenting the time required for esophageal, gastric, and small bowel passage.

The M2A™ Capsule Endoscope has demonstrated the ability to diagnose difficult and challenging small bowel cases where conventional methods have failed. There is significant promise for this technology to provide diagnostic information that changes patient management in a broad range of clinical situations including Crohn disease, celiac disease, irritable bowel syndrome, small bowel tumors and malabsorption. This new technology offers the patient and GI team a potential solution for the frustrations that have resulted from the unresolved diagnostic challenges of small bowel disease.

Acknowledgment

The author thanks Deborah Mutter, Executive Research Assistant, Given Imaging, Inc., for help in referencing citations.

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