The Preliminary Capsule Endoscopy Experience at Ochsner Clinic Foundation

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Diagnostic capabilities for the small bowel have made a giant leap forward this year with the release and availability of the M2A Video Capsule by Given Imaging, Ltd. (Yoqneam, Israel). This technology is most applicable to the patient with unexplained gastrointestinal bleeding. The patient swallows the capsule, which can take continuous digital images of the gastrointestinal tract for the life of the self-contained battery. In April 2002, Ochsner Clinic Foundation began making this available to patients and referring physicians. Our experience with the first 19 cases is described.

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 ↑ he field of gastrointestinal endoscopy has witnessed many advances in the last several decades. Modern endoscopy, specifically esophagogastroduodenoscopy and colonoscopy, allows excellent visualization of the upper gastrointestinal tract and colon and allows the operator to intervene in a wide variety of circumstances, for example snaring and removing polyps and achieving hemostasis from bleeding peptic ulcers. The small bowel, however, remains the region that still poses considerable challenges in the diagnosis and management of conditions that arise there. Contrast radiographic studies, specifically the upper gastrointestinal small bowel series, have been utilized to study this area, and while it is excellent for characterizing the gross abnormalities of Crohn's disease for instance, it cannot diagnose an arterio-venous malformation, which is the most common cause of bleeding referable to the small bowel. By using a technique known as push enteroscopy, the endoscopist uses a specific enteroscope to visualize the proximal 50 cm of the small intestine. Therefore, because the small intestine is 500 cm in length, there is obviously a major limitation to viewing all of the possible areas of disease with the available instruments.

Diagnostic capabilities for the small intestine made a giant leap forward this year with the release and availability of the video capsule by Given Imaging, Ltd. (Yoqneam, Israel). This phenomenal technology has placed a color camera, lens, light emitting diodes, and transmitter all within an easy to swallow capsule measuring $11 \text{ mm} \times 26 \text{ mm}$. The capsule, once activated and swallowed, transmits two images each second for the 7+ hours of battery life, with the data storage in a recorder worn as a belt by the patient during the study. The images are downloaded to a computer after the study where the interpreting physician can review it anytime thereafter.

Many investigators around the world have begun studies to verify the usefulness of the video capsule technique. Most studies have specifically looked at patients with unexplained gastrointestinal bleeding. Drs. Blair Lewis and Paul Swain, international experts in the field of gastrointestinal bleeding, have reported their initial experience with 21 patients (1). All of these patients had experienced severe ongoing bleeding that had defied diagnostic evaluation. The capsule identified a small bowel source of bleeding in 55%, with the most common diagnosis being the arterio-venous malformation (AVM). More studies were reported at the May 2002 Digestive Disease Week in San Francisco. A German study of 32 patients with chronic gastrointestinal bleeding found that the video capsule detected a definitive source in 62% (2). At this same meeting, Dr. Lewis updated his initial report to a total of 75 patients undergoing capsule endoscopy (3). With similar conclusions, a small bowel diagnosis was achieved in 59%. Genowsky et al of Boston reported an even higher yield of 74% when they studied 39 patients with

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gastrointestinal bleeding (4). This study went on to state that the diagnosis made by capsule endoscopy led to a change in management in 59% of patients.

OCHSNER EXPERIENCE

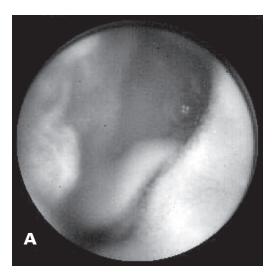
In the spring of 2002, Ochsner Clinic Foundation became the first center in the New Orleans area to make video capsule endoscopy available to patients. To date, 19 patients have undergone the procedure. As expected, the most common indication has been undiagnosed gastrointestinal bleeding. In three patients, a source of abdominal pain was being sought. Small bowel lesions were identified in five patients, a lower yield than reported in the literature. While the procedure has been well tolerated and the capsule itself easily swallowed, we have seen a problem with capsules not exiting the stomach in a timely fashion. In fact, for three patients the capsule remained in the stomach for the entire 7 1/2 hours of battery life. The capsule ultimately did pass in all three, but there was obviously no diagnostic value to the tests. All of these patients had a reason for decreased gastric motility, for example prior surgery and vagotomy. In one additional case, the capsule has remained in the small bowel, although it has not caused obstructive symptoms. Other lessons learned from our early experience are summarized in Table 1.

Table 1. Lessons learned in capsule endoscopy.

- Instructions from the company say that 2 hours after ingestion of the capsule the patient can have water, and at 4 hours a light snack can be consumed. We've had a problem with this, especially if the capsule took a while to exit the stomach. A sudden gush of food material renders the visibility of the capsule useless. We are currently recommending that the patient be allowed clear liquids, like apple juice, 4 hours after ingestion of the capsule, and we ask the patient to refrain from solid foods for the entire 8 hours.
- The physician interpreting the images afterwards can plan on 1 1/2 2 hours of time spent both in reviewing images and creating the report afterwards.
- Diabetic patients should consider having only clear liquids the evening before the study. Any decrease in gastric motility may create a problem in the passage of the capsule from the stomach into the small bowel. This might include prior gastric surgery or diabetic gastroparesis.

CASE REVIEW

A 77-year-old woman was referred specifically for consideration of capsule endoscopy. She had a past medical history significant for end-stage renal disease requiring dialysis, as well as coronary artery disease. For 2 years prior to presentation, she had experienced intermittent bleeding manifest as melena. Numerous conventional endoscopic procedures had been done. AVMs found in the stomach had been successfully cauterized, and it was believed that AVMs in the cecum were responsible for the recurrent bleeding. She was being considered for cecal resection at the time of the referral, because of ongoing significant transfusion requirements. Capsule endoscopy on this patient revealed several other AVMs in the small intestine (both distal and proximal) and actual active bleeding at two sites (Figure).



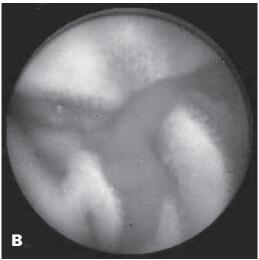


Figure. A. Large vascular lesion in the proximal small bowel. **B.** Several minutes later, in the same location, a gush of blood is seen emanating from the site.

Table 2. Public misconceptions about the video capsule.

- This technology is a substitute for colonoscopy for colon cancer and polyp screening. Although in some studies, the capsule will reach the colon before the 71/2 hours of battery life run out, the images in the colon are not very good. There is often stool in the cecal area. Also with the luminal diameter of the colon being greater than the small bowel, the light source from the capsule is unable to illuminate the entire field.
- The video capsule must be retrieved by the patient and returned. Specifically, the capsule does not need to be retrieved, and we certainly would not like it returned to us. All data storage occurs in the data recorder worn outside the patient.
- **CONCLUSION**

The video capsule system by Given Imaging, Ltd. represents the exciting first step in our attempts to visualize with clarity the small intestine. However, there are some problems associated with this new technology. It cannot specify the exact location of any lesion found, rather the physician can at best estimate based on transit time and visible landmarks, such as the pylorus and ileocecal valve. The physician time spent reviewing the thousands of images can be considerable as well. In my experience, it has taken about 90 minutes for each case. Some public misconceptions about this new technology are listed in Table 2.

Finally, although many states have adopted reasonable draft policies for Medicare coverage, Louisiana has not at this time. One would hope that a policy would be adopted in the future given the preponderance of data supporting the clinical utility of this technique. Nonetheless, it is exciting and rewarding to be able to offer patients hope for the successful diagnosis and treatment of disorders that have proven difficult to manage in the past. Most patients referred to date have been transfusion-dependent for their ongoing blood losses, although this is not a specific requirement. This technology should be considered for patients with ongoing and significant gastrointestinal bleeding, either overt and episodic or occult.

REFERENCES

- 1. Lewis BS, Swain P. Capsule endoscopy in the evaluation of patients with suspected small intestinal bleeding: the results of a pilot study. In press: Gastrointestinal Endoscopy 2002.
- Remke S, Helou L, Mayer G, et al. Wireless capsule endoscopy and push enteroscopy in chronic gastrointestinal bleeding: a prospective control trial. Gastrointestinal Endoscopy 2002; 55:AB125.

- 3. Lewis BS. Capsule endoscopy in clinical practice. Gastrointestinal Endoscopy 2002; 55:AB125.
- Genowsky D, Toth L, Wolff R, et al. Video capsule endoscopy: early observations on its role in the diagnosis and management of obscure gastrointestinal bleeding. Gastrointestinal Endoscopy 2002; 55:AB128.



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