Summary

✓ The Given M2A® ingestible, disposable imaging capsule contains a miniature video camera, which, when it is swallowed, can transmit images to a computer. It is used to detect abnormalities in the inner lining of the small intestine.

✓ In studies of small numbers of patients, the capsule demonstrates superior diagnostic rates for disorders of the small intestine among adults and children.

✓ All studies report fewer complications or less patient discomfort with the use of the capsule.

✓ Limiting factors are the time taken by physicians to evaluate the images, the lack of comparative evaluations of the capsule’s sensitivity and specificity compared to conventional procedures and the impact of its cost.

The Technology

The M2A Wireless Capsule Endoscope is manufactured in Yoqne’am, Israel, by Given Imaging Ltd. It is used to visualize the inner lining of the small intestine (SI), including regions that cannot be reached by traditional endoscopy, so that localized disorders may be diagnosed.

This video capsule endoscope (VCE) imaging system is disposable and wireless. It measures 11 mm by 26 mm and contains a camera, lens, light source, battery (with eight hours of recording time capability) and transmitter. After an overnight fast, the patient swallows the capsule with water. He or she can continue with regular daily activities, while the capsule travels through the gastrointestinal (GI) tract, transmitting images to a series of sensors attached to the abdomen. By tracing the capsule’s location during its journey using a localization algorithm, problem sites can be identified. The capsule is naturally expelled by the body eight to 72 hours after ingestion.

Eight hours of images (taken at two frames per second) are stored on a Walkman-sized data recorder that is worn around the patient’s waist. The 50,000+ images that are collected are downloaded onto a computer for analysis.

A blood sensing algorithm has been developed to facilitate the detection of blood in the SI, a common problem that is often difficult to detect and localize.

Regulatory Status

Health Canada issued the Given M2A Capsule Endoscope a class II (low risk) medical licence in July 2001. It has been available for use in Canada since November 2001. It is licensed for the detection of pathologies as an adjunctive tool in the diagnosis of GI disorders and diseases (Kathleen Savage, Therapeutic Products Directorate, Ottawa: personal communication, 2003 May 22). As of August 2001, it had also been approved for use in a number of countries including the US and the UK (Jenefer Pardy, Southmedic Inc., Barrie, ON: personal communication, 2003 May 12).

Distribution in Canada is controlled by Southmedic Inc. located in Barrie, Ontario. Several private clinics and 13 hospitals in Canada use this technology (Jenefer Pardy: personal communication, 2003 May 12).
Patient Group

VCE technology can be used by patients with SI abnormalities. A complete SI examination, which is often required to detect a physical abnormality, can be difficult and uncomfortable because of the small bowel’s length (5 m) and its many complex loops. Current diagnostic tools cannot reach the mid to distal areas of the small bowel, while VCE is able to image abnormalities previously undetected by conventional methods. This technology may be important for those patients with ongoing GI bleeding from an obscure source, particularly in cases where conventional methods yield no diagnosis. This technology has been used to successfully diagnose Crohn’s disease, Meckel’s diverticulum, small bowel polyps and chronic bleeding.

Current Practice

Several techniques are used to diagnose small bowel pathology, including barium follow through, push enteroscopy (PE), enteroclysis, angiography and nuclear scanning. A barium follow through, which is the traditional radiographic means of diagnosing SI neoplasms, cannot be used to diagnose the most common flat lesions and has low sensitivity for raised lesions. PE has a higher diagnostic rate, but it can only view the first 2 m to 3 m of the SI. PE involves the oral insertion of flexible fibre-optic cables, which are advanced into the stomach and then into the bowel. The procedure can also be used to obtain biopsies and conduct other treatment-related procedures. However, it usually requires sedation, can cause discomfort and result in pharyngeal or esophageal perforation.

The Evidence

Several studies compare the diagnostic abilities of VCE to those of barium follow through (Table 1) and of PE (Table 2). In all cases, VCE has the highest diagnostic yield (i.e. detection frequency of clinically relevant intestinal abnormalities). VCE is significantly better than barium follow through for diagnosing obscure GI bleeding and Crohn’s disease. Compared with PE, VCE has a significantly higher diagnostic yield for chronic and obscure GI bleeding and identifies bleeding sites beyond the range of PE. All these studies also report fewer complications or less patient discomfort associated with VCE.

Two additional studies evaluate the diagnostic yield of VCE alone. A diagnostic yield of 63% is reported for 35 patients with GI bleeding, while a diagnostic yield of 71% is reported for 17 patients with Crohn’s disease.

Adverse Effects

VCE is not recommended for patients with a swallowing disorder, a cardiac pacemaker or other implanted electro-medical devices, obstruction or strictures or fistulas that could delay the passage of the capsule or cause it to become lodged in the GI tract. Studies suggest that VCE is a safe diagnostic tool for patients with functional disorders of pyloric (stomach) motility. Eight clinical trials assess the complication rates of VCE use. Among the 187 patients evaluated in these trials, there were three reports (<2%) of complications. In each case, the capsule had to be surgically removed. In over 10,000 ingestions, however, only 0.75% of the capsules were not excreted naturally.
Administration and Cost

The complete VCE setup requires a supply of single use capsules (C$850/capsule) with at least one data recorder, a sensor array and the computer workstation (C$40,000) (Jenefer Pardy: personal communication, 2003 Nov 28). Cost estimates must also include the physician’s time for image evaluation, which can take one to two hours.  

One US economic analysis, which was funded by Given Imaging Ltd., concluded that VCE’s per unit cost as a diagnostic tool for SI bleeding was comparable with that of other current endoscopic procedures. For example, the average direct cost was US$517 for VCE and US$590 for enteroscopy.

Concurrent Developments

There are no similar products licensed for use in Canada. Clinical trials of the Norika v3, a capsule endoscope developed in Japan, are scheduled to begin in 2003. This capsule is smaller (9 mm by 23 mm), powered by microwaves, costs about a third of the price of the Given M2A and provides higher resolution images at a faster rate.

Implementation Issues

The literature shows that VCE offers a safe, painless and effective method of diagnosing abnormalities in the SI. Current technologies can be uncomfortable, require sedation and carry the risk of organ injury, including perforation.

While VCE is not designed to replace standard endoscopic examinations, it may save patients from more intrusive diagnostic procedures and occasionally preclude exploratory surgery. It has been useful in the planning of subsequent therapy. Most studies have assessed diagnostic yield. Further investigations need to assess the specificity and sensitivity of the device in comparison with conventional procedures. Its clinical significance also needs to be evaluated. The physician’s time spent in image evaluation may be the most costly component of VCE technology. An independent economic analysis, conducted from a Canadian health care perspective, is needed and it must account for equipment costs and the physician’s time.

References


