Given® Diagnostic Imaging System

Technology: Given® Diagnostic Imaging System
Manufacturer: Given Imaging Ltd., Yoqneam, Israel
Purpose: Diagnostic imaging of the small intestine

Current Regulatory Status: The Given® Diagnostic Imaging System was issued a Class II medical licence by Health Canada in July 2001, for the detection of pathologies as an adjunctive tool in the diagnosis of gastrointestinal disorders and diseases (Dorothy Corbett, Health Canada, Ottawa: personal communication, 2001 Nov 14). The device is distributed in Canada by Southmedic (Barrie, ON). The U.S. Food and Drug Administration (FDA) granted marketing approval for the Given® Diagnostic Imaging System (the M2A™ ingestible camera, data recorder and RAPID™ Workstation) in August 2001. Given Imaging has also received approval to market the system in Israel, the European Union and Australia.

Description: The M2A™ imaging capsule is 11mm x 26mm in size. It includes an optical dome, lens, illuminating disk, imager, battery, transmitter and antennae. The capsule is smooth and is easily swallowed. Once ingested, the device travels through the small intestine, capturing two images per second and transmitting video signals that are received by relay sensors attached to the patient’s body. The sensors send signals to a wireless data recorder in a belt worn by the patient. After image recording is complete, data are downloaded from the recorder to a workstation that produces a video record of the images from the small intestine. The capsule battery life is about eight hours, which is sufficient for imaging the small intestine, but not long enough to provide images of the large intestine. The device is excreted in eight to 72 hours.

Cost: The cost of each single-use M2A™ capsule is about C $900. The RAPID™ Workstation costs about C $25,000 and the data recorder is approximately C $10,000 (Robert Sutherland, Southmedic, Barrie (ON): personal communication, 2001 Nov 14).

Evidence of Efficacy and Safety: The approval by the FDA was linked to the results of a small, non-randomized study comparing the use of the M2A™ capsule to conventional endoscopy. The study included 20 patients who had an inconclusive diagnosis after previous endoscopic and radiological procedures to identify the source of internal bleeding. The M2A™ capsule detected intestinal lesions in 12/20 subjects (60%) compared to 7/20 (35%) detected by the use of endoscopy. In five cases, the capsule was able to identify the source of bleeding in a region of the small intestine that could not be reached by an enteroscope (an endoscopic instrument using a narrow, flexible tube passed through the mouth to the upper digestive tract). A preliminary report on nine patients indicated that the imaging pill detected all lesions found by the enteroscope, and also identified several additional lesions that were beyond the reach of the enteroscope.

The technology is said to be safe as long as there is no narrowing or blockage in the intestine. It is also contraindicated for patients with cardiac pacemakers or other implanted electromagnetic devices. The manufacturer’s web site states that, to date, no side effects have been found with use of the capsule according to their guidelines.
The device is currently being used in two clinical trials in Canada: a pediatric trial of 30 children at Ste. Justine Hospital, in Quebec, and a trial in 20 adult patients with Crohn's disease and celiac disease, at St. Michael's Hospital, in Ontario. Several other Canadian hospitals have plans to acquire this technology (Robert Sutherland, Southmedic, Barrie (ON): personal communication, 2001 Nov 14).

Available Alternative Technologies:
Standard approaches for investigation of the small intestine are endoscopic and radiological examinations. As flexible enteroscopes cannot reach all of the small intestine, exploratory surgery and intraoperative endoscopy are options for cases where the source of bleeding cannot be determined.

Commentary:
This technology is a significant extension to the methods available for examination of the small intestine. Its use may be mainly in major centres with expertise in gastrointestinal endoscopy. Review of the video images requires considerable physician time and experience. Patient reports indicate the imaging capsule is preferred to traditional endoscopic procedures.

References:

This summary was prepared by David Hailey and Leigh-Ann Topfer, CCOHTA.
The contents of this bulletin are current as of November 2001.
This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.
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