Two Clinical Studies Recommend Use of PillCam SB as Screening Tool for Diagnosing Cause of Iron Deficiency Anemia

Given Imaging Ltd. announced two studies concluding that PillCam SB capsule endoscopy is a modality of choice in diagnosing the cause of unexplained iron deficiency anemia (IDA) following negative endoscopy and can lead to a definitive diagnosis in this group.

The National Institutes of Health (NIH) estimates that 20% of women and 3% of men in the United States have IDA. Iron is an essential component of hemoglobin, the oxygen-carrying pigment in the blood. The causes of iron deficiency are too little iron in the diet, poor absorption of iron by the body, and loss of blood (including from heavy menstrual bleeding). According to the NIH, in men and postmenopausal women the cause of IDA is usually GI bleeding associated with ulcers, use of non-steroidal anti-inflammatory drugs (NSAIDs) or cancer. Published literature shows that patients may undergo up to seven procedures before a definitive diagnosis is made.

A 253 patient prospective study led by Periklis Apostolopoulos, M.D., from Athens, Greece, sought to investigate the value of PillCam SB in detecting small bowel lesions likely to cause anemia. Patients included had unexplained IDA and had undergone negative gastroduodenoscopy (upper endoscopy) plus biopsies and ileocolonoscopy (colonoscopy) procedures. PillCam SB detected a likely cause of the symptoms in 57% of these patients.

"While traditional diagnostic methods for IDA are effective, the cause of IDA remains undetected up to 30% of the time. The data from our study concludes that using PillCam SB can lead to definitive diagnoses of the underlying causes of unexplained IDA in this group of patients," said Dr. Apostolopoulos.

Between December 2003 and December 2004, 253 patients with a median age of 57 years were referred for unexplained IDA and received an upper endoscopy with biopsy and a lower endoscopy. Endoscopic/histological tests in 51 of these patients (20.1%) were negative and PillCam SB was subsequently performed. This patient group was also rigorously screened to exclude other possible causes of blood loss. The PillCam SB found one or more small bowel lesions likely to cause IDA in 29 patients (57%). To confirm the PillCam SB findings, investigators performed air double-contrast enteroclysis (EC) following PillCam SB and found abnormal findings in only 6 of 51 patients (11.7%) of patients.

A second, unrelated study led by Waseem Ashraf, M.D. and colleagues at King George Hospital in London mirrored these results. Designed to assess the diagnostic yield of PillCam SB in patients referred for unexplained IDA and other GI conditions, in 48 patients who completed the study, the cause of IDA symptoms was identified in 27 (56.0%). Positive findings in patients with unexplained IDA included Crohn’s disease (6), tumors/polyps (4), of which 2 were confirmed to be malignant, angiodysplasia (4), NSAID-related ulcers (2) and intestinal worms.

The investigators confirmed previously-reported findings that PillCam SB detects and visualizes small bowel problems not detected in patients with IDA and suspected occult GI blood loss that had undergone extensive diagnostic investigation. The findings also showed a high incidence of Crohn’s disease and small bowel tumors in these patients.

Dr. Ashraf and his research team concluded that PillCam SB should be the diagnostic modality of choice following a normal upper GI endoscopy and colonoscopy in patients with unexplained IDA and occult gastrointestinal bleeding.

Advance Multi-Matrix System Technology May Allow for First Once Daily Dosing of Mesalamine in Ulcerative Colitis (UC), a Form of Inflammatory Bowel Disease (IBD)

Results of a randomized, multi-center, double blind parallel group dose ranging study of an advanced formulation of high-strength mesalamine, SPD476, were presented at the World Congress of Gastroenterology in Montreal, Canada.

Mesalamine is routinely used for the treatment of UC. SPD476 utilizes an advanced Multi-Matrix System™ (MMX) technology to provide the highest mesalamine doses per tablet and is being investigated to see if it delivers mesalamine consistently throughout the colon.
The study was intended to provide information on SPD476 given once daily over an eight week time period. Patients with mildly-to-moderately active UC received 1.2 g, 2.4 g or 4.8 grams of SPD476 once daily. An endpoint of induction of remission was used to evaluate patients. Remission was defined as complete resolution of symptoms combined with improved endoscopy score. Patients who received 2.4 and 4.8 grams showed response to the treatment, and no patients in the study withdrew due to adverse events. The most common adverse events reported with SPD476 were gastrointestinal disorders and headaches.

“These results are encouraging because they demonstrate the ability of a novel formulation of mesalamine to induce remission when given once-a-day, something being investigated in clinical studies for the first time,” said Dr. Patrick Connor, one of the lead investigators in the study. “Data from this trial provide the foundation for further study of SPD476 as a once daily treatment for ulcerative colitis.”

Studies of UC patients have demonstrated that up to 68% of patients do not regularly take the medication needed to control their condition, despite orders from their doctors (1).


World Gastroenterology Organisation Creates Seven International Training Centers on Three Continents To Train Physicians in Developing Countries

In a bold and pioneering humanitarian effort, the World Gastroenterology Organisation (WGO-OMGE), in partnership with the World Organization for Digestive Endoscopy (OMED), has established seven international medical training centers to bring advanced physician training to developing countries on three continents. WGO-OMGE and OMED are the only nonprofit medical organizations worldwide to establish training centers where physicians can go to learn the latest medical procedures in digestive health. Experts in a particular area of gastroenterology volunteer to train doctors to improve their own practice and teaching at home. Partnering with local staff and

physician volunteers from around the world, WGO-OMGE develops global programs for the improvement of digestive health in various regions around the world and, especially, in developing countries.

To date, more than 500 doctors from more than 40 countries have been trained. A substantial amount of endoscopic equipment has been supplied and trainees have enjoyed training ranging from 2 weeks to 2 years through the joint WGO-OMGE/OMED program.

“Access to high quality medical training in advanced procedures is still inconsistent in various areas of the world. Because of economic hardship, health practices often lag behind what is currently available in more economically advanced regions,” said Eamonn Quigley MD, FRCP, FACP, FACG, FRCPI (Ireland) President-Elect of the World Gastroenterology Organisation. “There are huge gaps in the availability and practice of medical procedures. Our goal is to bring high quality training and medical equipment to ALL areas of the world.”

Courses at the WGO-OMGE/OMED Training Centers are designed to supplement training provided in the home country and do not attempt to provide a complete training in gastroenterology. The courses are based on a defined curriculum developed by the local gastroenterological society and the WGO-OMGE/OMED Education and Training Committee to reflect the health needs of the area and based on a caring and ethical approach to patient care. Didactic components review both basic science relevant to gastroenterology and practical instruction in endoscopy and other important procedures are provided through interactive video- and computer-based programs, as well as live patient demonstrations.

“We aim to provide access to training in the most current medical procedures in digestive medicine and build an infrastructure of training centers and training workshops so that our efforts continue for the long term and not just as a ‘one shot deal’,” said James Toouli MBBS, PhD, FRACS (Australia), Chair of the World Gastroenterology Education and Training Committee. “Our goal is to ensure training is available globally, not just in the most economically developed countries. We are obliged to bring high quality medical care to all areas of the world, despite the challenges.”
The benefit of the Training Centers program is greater access to life-improving and in some cases life-saving procedures. As each doctor undergoes rigorous hands-on training in these WGO-OMGE/OMED Training Centers they can then return to their own region, and, in turn can train other doctors. Thus, these training centers have an invaluable long-term ripple effect.

Practicing gastroenterologists and surgeons spend periods of 3–12 months learning advanced therapeutic and diagnostic techniques in endoscopy, colonoscopy, endoscopic ultrasonography and other medical procedures. Trainees are charged no fees and attending physicians donate their time. Almost 100 percent of the equipment and supplies used at the centers has been donated. The Centers also participate in electronic learning by making complex cases available via the WGO-OMGE website.

The WGO-OMGE/OMED Education and Training Committee commits considerable efforts to the establishment of these centers and provides initial and subsequent annual funding. The ultimate goal for all of these centers is that they should become financially self-sufficient, based on funds raised from local and regional sponsors. It is hoped that with an increasingly secure financial basis, the scope of activity of the center can expand, the duration of administered courses can be extended and their frequency increased. The WGO-OMGE/OMED Education and Training Committee is committed to working with the local gastroenterological society and authorities to providing on-going academic leadership.

**Background Information on the WGO-OMGE/OMED Training Centers**

There are two types of WGO-OMGE/OMED Training Centers. Broadly based educational centers have been developed in South Africa, Morocco, Egypt, Pakistan and Bolivia. These centers aim to educate on the broad aspects of gastroenterology including basic and specialized endoscopy. This is done primarily via attachments of trainees for varying periods of time up to two years so that not only cognitive training occurs but also hands on. The centers also conduct focused workshops which enhance the experience and cater for a larger group of gastroenterologists over a shorter period of time.

Advanced centers in Endoscopy training have been recognized in Chile and Italy. These centers provide training in the more advanced and specialized aspects of endoscopy and cater for individuals not only from the developing world but also for gastroenterologists and GI surgeons from any of the member countries of the WGO-OMGE. The crucial aspect of the experience is that the center provides hands on training in the procedural aspects of endoscopy. Numbers who can be trained are necessarily small and hence there is a waiting period before trainees can be accepted in to these advanced centers.

There is no charge to the physician being trained and often assistance is provided with accommodations.

**Funding:** In addition to the direct funding by the World Gastroenterology Organisation and the World Organization for Digestive Endoscopy generous financial supports has been provided by several pharmaceutical and medical manufacturing companies.

**Goals of the Training Centers**

- To promote the highest standards in training in gastroenterology and endoscopy in a selected region
- To develop a curriculum for training in gastroenterology based on current science, ethical principles and relevant to local and regional health care needs
- To expose young gastroenterologists-in-training to the most current knowledge in gastroenterology
- To foster interactions between international and regional experts in the field of gastroenterology
- To promulgate best practice guidelines in gastroenterology and endoscopy

**The WGO-OMGE/OMED Training Center Concept**

It is important to note that the Centers should not be seen as opportunities to run conferences. Instead, they should fulfill educational needs for gastroenterologists of a specific region. These needs may take a variety of strategies: Specific workshops; Training of doctors, nurses and health care workers from surrounding countries; Running Master Classes in endoscopy so as to introduce new techniques to regions where these do not exist; and Support ongoing training of physicians and surgeons who have not trained in gastroenterology.