

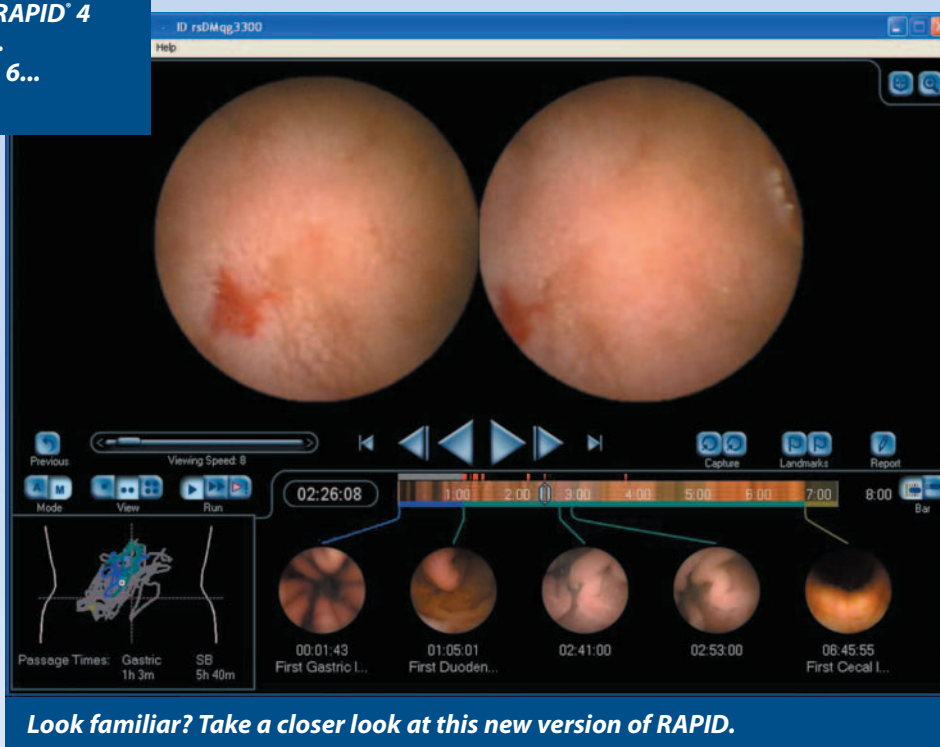
New RAPID® 4 Software

Powerful Features for More Efficient Reading and Increasing Diagnostic Confidence

Now available worldwide, RAPID® 4 is the next-generation software for the PillCam™ Platform—Given Imaging's user-friendly, clinically-proven tool for capsule endoscopy. Utilizing the RAPID software, Given® Workstation and PillCam™ SB and PillCam™ ESO video capsules, the PillCam Platform provides accurate visualization of the GI tract in its natural state. Intensive collaboration with users has resulted in product innovations in RAPID 4 that increase workplace efficiency and diagnostic confidence.



David Rubin, MD (USA) comments on the new RAPID® 4 software. See page 6...



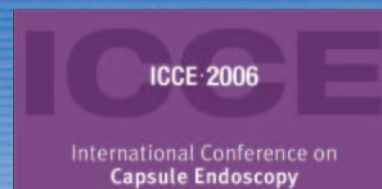
Look familiar? Take a closer look at this new version of RAPID.

What's new in RAPID 4?

- **Automatic Mode v4**—An aid that smoothes diagnostic review for increased reading efficiency.
- **QuickView v4**—Fast preview of the video while highlighting images that may be of interest in the video stream.
- **RAPID® Atlas**—Integrated, reference atlas of PillCam images searchable by findings, diagnosis or Capsule Endoscopy Structured Terminology™ (CEST™); enables comparing on-screen actual case images to images in RAPID Atlas.
- **Circumference Scale**—A tool for assessing circumferential involvement of findings such as esophageal varices or small bowel ulcers.

continued on page 6...

- **Grand Rounds:** Unresolved Iron-Deficiency Anemia—Definitive Diagnosis of TB
- **Grand Rounds:** Detecting Esophageal Cancer—Screening Patients with GERD and Barrett's Esophagus
- **CE and Double-Balloon Enteroscopy**
- **Satellite CE Study Data Presented at UEGW**
- **ICCE 2006**
- **Regulatory Affairs Professionals Society Award**
- **Japanese CE Image Atlas**




The Impact of ICCE™

Published last fall in *Endoscopy* after the International Conference on Capsule Endoscopy™, the ICCE Consensus has established a scientific baseline and is already making an impact on clinical practice.

continued on page 6...

Third-generation PillCam™ SB Video Capsule

Given Imaging recently announced  development of a third-generation PillCam SB™ video capsule for the small bowel. Doubling the frame rate to 4 frames/sec, the new PillCam SB will offer enhanced viewing capacity, increase operational time and incorporate new optical and image-sensor technology for superior imaging. This technology will also be used in a future version of PillCam ESO for imaging the esophagus as well as the PillCam COLON, currently in clinical trials. The new PillCam SB video capsule will be commercially available later this year—more information in our next issue of the *GI insider*.



Grand Rounds

Unresolved Iron-Deficiency Anemia

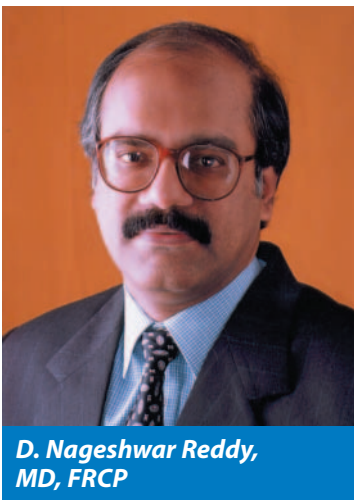
CE with PillCam™ SB Enables Definitive Diagnosis: A

by **D. Nageshwar Reddy, MD, FRCP**

Professor of Gastroenterology, Director, Asian Institute of Gastroenterology, Hyderabad, India

Rajesh Gupta, MD, DM

Assistant Professor of Gastroenterology, Consultant Gastroenterologist, Asian Institute of Gastroenterology, Hyderabad, India



**D. Nageshwar Reddy,
MD, FRCP**



Rajesh Gupta, MD, DM

The clinical presentation of intestinal tuberculosis varies from minimal nonspecific symptoms to chronic diarrhea, weight loss, fever, overt or occult GI bleeding, and unresolved iron-deficiency anemia (IDA). Intestinal tuberculosis (TB) is prevalent in developing countries including India and continues to be a global threat, according to the WHO (see Editor's note). We present a case of unresolved iron-deficiency anemia where capsule endoscopy enabled a definitive diagnosis of intestinal tuberculosis.

Editor's note: The World Health Organization (WHO) declared TB to be a "global health emergency". The disease is spreading at the rate of one person per second. Every year 8–10 million people catch the disease and 2 million die from it. About a third of the world's population, or around 2 billion people, carry the TB bacteria but most never develop the active disease. Around 10% of people infected with TB actually develop the disease in their lifetimes, but this proportion is changing as HIV severely weakens the human immune system and makes people much more vulnerable. This global situation is further complicated by the migration of people infected with TB bacilli to regions where TB had been virtually eliminated and the emergence of strains of drug-resistant TB.¹⁻³

Case History

A 33-yr old male presented with weakness, decreased appetite and intermittent loose stools for last 6 months. His physical examination was unremarkable except unresolved iron-deficiency anemia. His laboratory investigations revealed Hb 9.2 gm% with normal liver function tests (LFT) and kidney function tests (KFT). Chest X-ray and abdominal ultrasound (US) were normal. Patient was treated with oral iron preparations and showed only partial improvement. He was referred to our institute for further evaluation.

Previous Diagnostic Procedures and Treatments

- Esophagogastroduodenoscopy (EGD): Normal study.
- Colonoscopy: Normal study.
- Duodenal biopsy: No abnormality detected.
- Small bowel follow-through (SBFT) contrast radiography: No abnormality detected.

PillCam™ SB Findings

Capsule endoscopy with the PillCam SB video capsule showed multiple-focal aphthous ulcers starting from proximal ileum to distal ileum (see PillCam SB images right). Jejunum was normal.



Case of Intestinal Tuberculosis

Patient Management and Follow-up

Based on CE findings using the PillCam SB, patient underwent ileoscopy which confirmed aphthous ulcers in distal ileum. The biopsy taken from ileum showed granuloma with giant cells in lamina propria (see Histopathology image). The ileal biopsy was also sent for microbacterial tuberculosis-polymerase chain reaction (MTB-PCR) which was positive, confirming the diagnosis of tuberculosis. Patient was treated with anti-tubercular drugs for 6 months. Follow-up CE examination after 9 months of anti-tuberculosis therapy showed mucosal healing and normal small bowel—patient recovered completely and is doing well.

Conclusions

This case demonstrates the importance of CE as a screening tool for patients with iron-deficiency anemia. Capsule endoscopy with the PillCam SB video capsule helped in arriving at the correct diagnosis in this particular case—and as a result, helped save the patient's life.

About the Authors

Dr D. Nageshwar Reddy, Professor of Gastroenterology, is Chief Gastroenterologist to Medinova Diagnostic Services and Director of Asian Institute of Gastroenterology in India. He has held a number of visiting professorships including at Boston University Medical Center, Chinese University in Hong Kong, Fujigoka University in Tokyo and University of Brussels. Dr Reddy has been performing CE with the PillCam SB since 2002 and is involved in ongoing clinical trials. He has received awards from GI professional societies in Japan, Southeast Asia region and the USA—as well as international social service awards for contributions to community and global healthcare. His advanced therapeutic endoscopy training center has provided training for over 400 physicians from around the world. Dr Reddy, author of several books on Gastroenterology, also serves on the Editorial Board of the International Journal of Digestive Endoscopy, International Advisory Board to the Japanese Society of GI Endoscopy, GastroHep.com Global Academic Faculty, and is a panel leader for ICCE 2006.

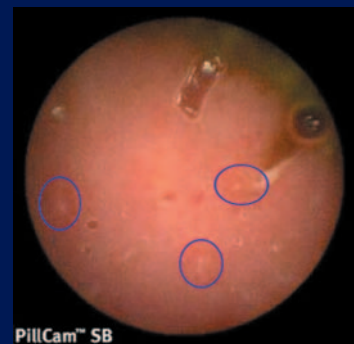
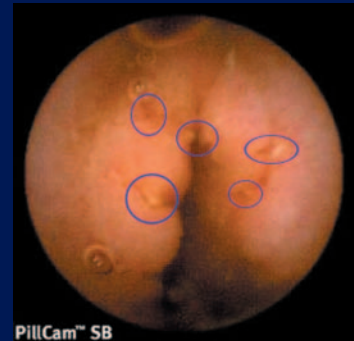
Dr Rajesh Gupta, Assistant Professor of Gastroenterology, is a Consultant Gastroenterologist at Asian Institute of Gastroenterology and has been performing capsule endoscopy since 2004. Dr Gupta has been actively involved publishing his experience on capsule endoscopy.

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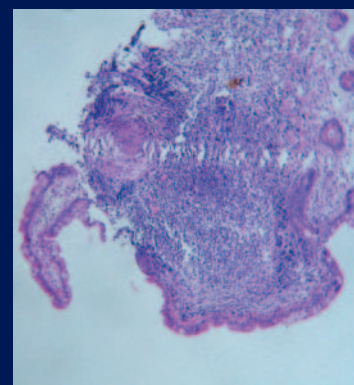
Unresolved Iron-Deficiency Anemia

Diagnosis: Intestinal TB



Multiple-focal, aphthous ulcers found in proximal ileum to distal ileum.

Histology



Ileal biopsy showing granuloma with giant cells; ileal biopsy was also sent for MTB-PCR which was positive, confirming diagnosis of intestinal tuberculosis.



Grand Rounds

Detecting Esophageal Adenocarcinoma: PillCam™ ESO for Screening Patients with GERD

by **Jean Boyer, MD, PhD**

Professor of Medicine, Chief of Hepatogastroenterology, University Hospital of Angers, Angers, France

Vincent Quentin, MD

Hepatogastroenterology Unit, University Hospital of Angers, France



Jean Boyer, MD, PhD



Vincent Quentin, MD

This Grand Rounds is based on a live capsule endoscopy case session at the most recent Video-Digest conference, which is held annually in France.

Editor's note: Approximately 1 in 4 Americans suffers from GERD, 10% also have Barrett's esophagus—so about 1 to 2% of the adult population has a pre-malignant condition putting them at risk for esophageal adenocarcinoma. This cancer has the most rapidly rising incidence of any cancer in the last 30 years. For more information on the rise in esophageal cancer and the cascade of GERD to Barrett's esophagus to adenocarcinoma, see page 6 of GI insider, Vol. 2 No. 2, 2004 available at www.givenimaging.com.

Case History, Previous Diagnostic Procedures and Treatments

A 61-year old man presented with a history of gastroesophageal reflux disease (GERD) for 4 years.

Initial gastroscopy (EGD with anesthesia) enabled diagnosis of hiatal hernia and a 1.5cm-height strip of Barrett's esophagus (short-segment Barrett's esophagus). Biopsy was performed, confirming intestinal metaplasia with one focal point of low-grade dysplasia. After 6 months of proton pump inhibitor (PPI) therapy, repeat biopsy found no dysplasia. PPI therapy was continued. A monitoring EGD performed in October 2005 confirmed that Barrett's esophagus characteristics were unchanged, but pathologic examination revealed high-grade dysplasia.

The patient was admitted to our department for further investigation.

PillCam™ ESO Findings

Esophageal capsule endoscopy (ECE) with the PillCam ESO video capsule was performed in early November 2005 during the live case session at the annual Video Digest conference. While the strip of Barrett's esophagus was seen very well, ECE with PillCam ESO also revealed a nodular elevation of the esophageal wall under the strip of Barrett's mucosa. This finding had previously been undetected.

Patient Management and Follow-up

An endoscopic ultrasound investigation was performed with a 20 mHz mini-probe, revealing no infiltration and no suspect node. Mucosectomy was accomplished in two pieces: the strip of Barrett's esophagus and the nodular elevation. Pathologic examination showed adenocarcinoma with infiltration of muscularis mucosae in both pieces. Resection was considered on one side. Surgical treatment was proposed as curative option and scheduled for early 2006. Further follow-up will be determined based on definitive pathologic results.



and Barrett's Esophagus

Conclusions

This Grand Rounds case and new finding of esophageal cancer demonstrates the potential of PillCam ESO in screening patients with GERD and Barrett's esophagus. It also highlights the importance of ongoing multi-national studies and new data to be reported at the upcoming ICCE. This is especially important considering the alarming rise in esophageal adenocarcinoma, the fastest growing cancer in recent decades [see Editor's note].

Interestingly, after the live ingestion of the PillCam ESO video capsule and review of our findings at Video-Digest 2005, this case and image quality generated much interest throughout the remainder of the conference—especially since the patient had undergone screening via standard EGD to monitor his condition only a few weeks earlier. In this case PillCam ESO diagnosed a suspicious lesion earlier than EGD, probably improving the accuracy of surgery and patient's survival.

About the Authors

Dr Jean Boyer, Professor of Medicine, is Chief of the Hepatogastroenterology Unit at the University Hospital of Angers, France. Prof Boyer has been using CE since 2003. His GI practice focuses on endoscopic treatment of GERD and Barrett's esophagus; other interests include interventional endoscopy, ERCP and photodynamic therapy (PDT). He is currently participating in two French multi-center studies using the PillCam video capsule: PillCam SB for digestive bleeding and PillCam ESO for detecting pre-neoplastic lesions in the esophagus. Prof Boyer will be the Principal Investigator of the upcoming French multi-center prospective study using PillCam ESO for evaluating portal hypertension and detecting esophageal varices.

Dr Vincent Quentin is an endoscopy practitioner in the Hepatogastroenterology Unit at the University Hospital of Angers. Dr Quentin is also the hospital's PillCam Referent, performing and reviewing the hospital's CE studies with Prof Boyer since 2003. His main interests in clinical practice and research are interventional endoscopy and cancer of the GI tract. Dr Quentin is also an active participant in the French multi-center studies using the PillCam SB and PillCam ESO.

Barrett's Esophagus and Esophageal Adenocarcinoma



Barrett's esophagus (short-segment)



Nodular elevation of wall under Barrett's mucosa, suspicious of esophageal cancer, previously undetected by EGD. Pathologic examination: adenocarcinoma with infiltration of muscularis mucosae.



A Closer Look at RAPID 4

...continued from front page

New Features for More Efficient Reading:



Automatic Mode v4

An aid that smoothes diagnostic review for increased reading efficiency.

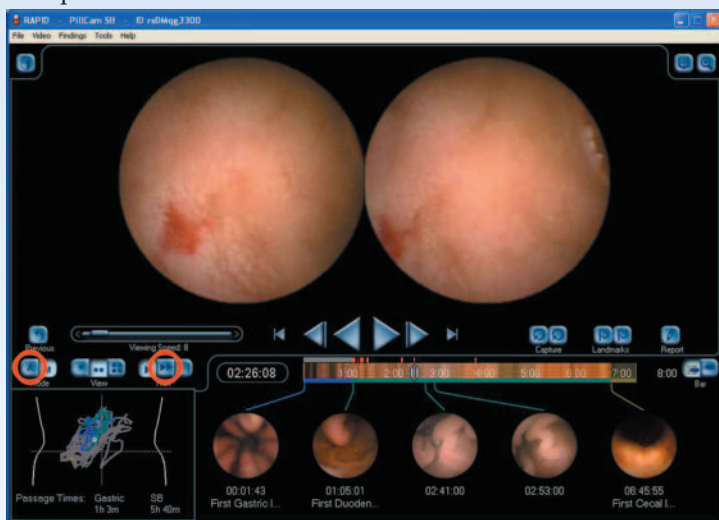
- Regulates rate of change in the small bowel video in order to make reading more comfortable.
- Uses advanced software to combine similar images rather than showing each one in sequence.



QuickView v4

Fast preview of the video while highlighting images that may be of interest in the video stream.

- QuickView v4 is a tool for video preview. It scans each frame to select the most significant images of interest within segments across the video and presents the selected images in a short video to provide an overview of the case prior to full review.
- A typical preview with QuickView v4 takes only a few minutes.



Automatic Mode v4 and QuickView v4 buttons
(PillCam SB images of active bleeding)

New Features for Increasing Diagnostic Accuracy:



Circumference Scale

A tool for assessing circumferential involvement of findings such as esophageal varices or small bowel ulcers.

- Activated in Report Editor.
- Useful to describe a finding, eg, how much of the image circumference is affected by the finding.



RAPID Atlas

Integrated, rapid review of PillCam images.

- Enables side-by-side comparison of images to improve diagnosis.
- All PillCam images are available in the RAPID Atlas.

reviewed and can be updated as new images become available.

- Searchable by findings, diagnosis, or Endoscopy Structured Terminology™ (CEST™).
- Easily accessible in RAPID from Main Screen or Report Editor.



Circumference Scale feature
(PillCam ESO images of esophageal varices)



"As a beta-site user for the new RAPID software, I've been delighted with the improvements and additions. Automatic Mode v4 makes reading easier because the PillCam video moves at a more even pace. QuickView v4 has made my reviews more efficient by allowing a quick overview prior to detailed reading. In addition, the RAPID Atlas with the side-by-side image comparison feature has been particularly helpful for my colleagues and our Fellows."

—David Rubin, MD, Assistant Professor of Medicine, Director of Clinical Education, University of Chicago, Chicago, Illinois, USA

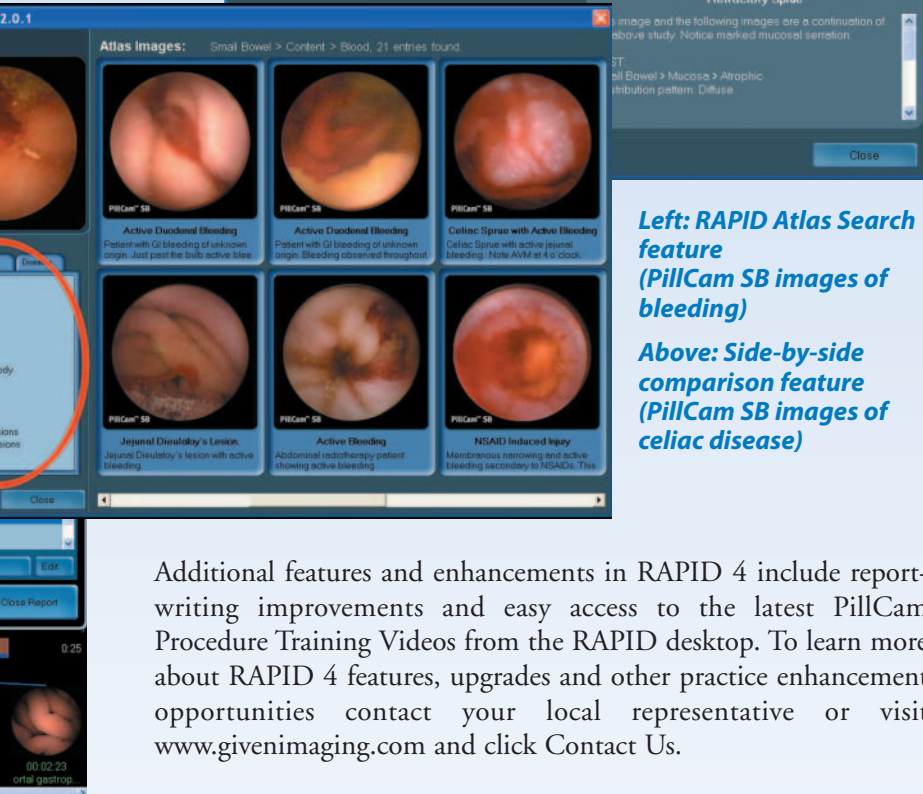
Diagnostic Confidence:

reference atlas of
images.

on-screen, side-by-
son of actual case
images in RAPID

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**Left: RAPID Atlas Search
feature
(PillCam SB images of
bleeding)**

**Above: Side-by-side
comparison feature
(PillCam SB images of
celiac disease)**

Additional features and enhancements in RAPID 4 include report-writing improvements and easy access to the latest PillCam Procedure Training Videos from the RAPID desktop. To learn more about RAPID 4 features, upgrades and other practice enhancement opportunities contact your local representative or visit www.givenimaging.com and click Contact Us.

What is CEST™?

Capsule Endoscopy Structured Terminology™ (CEST) is the result of ongoing work spanning several years by a global GI physician panel of capsule endoscopy experts to establish a common vocabulary for CE.

To learn more, see References at www.CapsuleEndoscopy.org for recent articles published in Endoscopy describing CEST and the development of the terminology for capsule endoscopy.

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...continued from front page

The Impact of ICCE™

The ICCE Consensus is being applied to help improve diagnosis and provide guidelines for clinical research. In the USA, Atlanta Gastroenterology Associates (AGA) is applying the ICCE Consensus in its 15 locations in Georgia. At ICCE 2006 Steve Morris, MD (USA), a physician at AGA and Assistant Professor at Emory University School of Medicine, will discuss the positive impact the ICCE Consensus has had on diagnostic work-up and outcomes, as well as practice management. In Japan the Capsule Endoscopy Study Group (CESG) is using the ICCE Consensus as guidelines for its research and clinical studies.

ICCE 2006

New this year is an expanded scientific program with a winter meeting in Florida and a summer meeting in Paris. Highlights of this year's conference and ICCE Consensus will be summarized in the ICCE Report; global distribution will begin at Digestive Disease Week® (DDW). Look also for important material on the ICCE component of www.CapsuleEndoscopy.org.

**Stay tuned for ICCE 2006 to learn
about the continuing progression of
clinical knowledge.**



**To register for the ICCE in Paris,
visit www.2006icce.com**

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Capsule Endoscopy and Your Clinical

CE and Double-Balloon Enteroscopy (DBE)

Where do CE and DBE fit in clinical practice? How are they complementary? Several leading GI physicians from around the world involved in researching CE and DBE in clinical practice provide their insight.

DBE was developed jointly by a research team at the Jichi Medical School in Japan led by Hironori Yamamoto, MD, PhD and Fujinon, Inc. The procedure can be performed with either an antegrade (upper) or retrograde (lower) approach; it requires sedation and a dedicated endoscopy room and team. DBE uses an endoscope, specialized balloons, balloon pump control and over-tube for positioning the endoscope. DBE technology, commercially available since August 2004 under the Double-Balloon Endoscopy™ brand, is designed to "allow physicians to endoscopically evaluate and treat disorders of the small intestine previously inaccessible without invasive surgery."¹



Hironori Yamamoto, MD, PhD,
*Assoc Professor, Department of
Gastroenterology, Jichi Medical
School, Japan*

At the Satellite Symposium "The Cutting Edge of Small Bowel Endoscopy—Capsule Endoscopy and Double-Balloon Endoscopy" at DDW-

Japan 2005 Drs Hironori Yamamoto (Japan) and Tetsuya Nakamura (Japan) gave keynote clinical presentations to approximately 900 attendees. Additionally, members of the Japan Capsule Endoscopy Study Group (CESG) in Japan (see page 11, *GI insider* Vol. 3 No. 2, 2005) presented their experiences in using CE and DBE as collaborative tools. The CESG uses the PillCam SB video capsule exclusively in its studies.

Dr Hironori Yamamoto, inventor of double-balloon endoscopy and author of publications on DBE²⁻⁴ since its development, sees double-balloon and capsule endoscopy as a "partnership"—with CE as the choice for screening and DBE as the best tool for therapy of small bowel diseases. "CE can help us localize pathology and reduce the burden to the patient by eliminating either the upper or lower endoscopies." Dr Yamamoto continued, "Surprisingly, in many cases DBE can provide feedback to the physician about his findings with CE and in this way improve the accuracy of the CE diagnosis."



Andrew Taylor, MD, FRACP,
*Department of Gastroenterology, St
Vincent's Hospital, University of
Melbourne, Melbourne, Australia*

In "Initial Experience Using Double-Balloon Enteroscopy in an Australian Tertiary Hospital" at Australian Gastroenterology Week (AGW) 2005⁵,

Dr Andrew Taylor (Australia) presented study data on indications for DBE, estimated distance for antegrade and retrograde approaches, findings, therapy performed, and prior CE results. Dr Taylor has been using CE since 2002 and DBE since 2004. He is Chairman of the Small Intestinal Symposium to be held in March 2006 at St Vincent's Hospital in Melbourne, which will include a number of sessions on CE with the PillCam SB and DBE techniques led by physicians from Australia and Japan.

Dr Taylor commented "Double-balloon enteroscopy is clearly part of the revolution in small bowel evaluation and treatment which has occurred during the last 5 years. Although it provides much greater depth of insertion than push enteroscopy, double-balloon enteroscopy is time-consuming and demanding for frail patients. PillCam remains the investigation of choice for obscure GI bleeding, with double-balloon enteroscopy reserved for therapeutic procedures or biopsy of lesions which appear within reach via the mouth or the colon."



**Jonathan Leighton, MD, Assoc
Professor, Director, IBD Clinic,
Division of Gastroenterology,
Mayo Clinic Arizona, USA**

At the recent ACG Governor's / ASGE Best Practices 2006 meeting, Co-Chairman Dr Jonathan Leighton (USA) summarized clinical data and the roles of the two technologies in his presentation "Capsule Endoscopy and

Double-Balloon Enteroscopy in the Diagnosis of Small Bowel Disorders." Dr Leighton has been using CE since 2000 and DBE since 2004. He has been actively involved in clinical studies and publications on CE⁶⁻⁸ for different indications including obscure gastrointestinal bleeding (OGIB) and IBD. He has been a participant in the ICCE Consensus on IBD

Practice

and recently published a meta-analysis of CE compared to other methods for OGIB.

According to Dr Leighton, "Capsule endoscopy remains an important, patient-friendly tool for initial diagnostic evaluation, also for localizing lesions in the proximal and distal small bowel. DBE allows for diagnostic and therapeutic interventions when a lesion is identified. Recent data suggest that there is significant agreement between DBE and CE in diagnosing AVMs, ulcers and large masses in patients with small bowel disease. At this time, these two tests appear to be complementary for the diagnosis and management of small bowel disease."



Simon Lo, MD, FACP, Director Pancreatic and Biliary Diseases Program, Cedars-Sinai Medical Center and Assoc Clinical Professor, David Geffen School of Medicine, University of California, Los Angeles (UCLA), California, USA

Results of the first multi-center study in the USA on double-balloon enteroscopy⁹ were presented at UEGW 2005 by Dr Simon Lo (USA), a pioneer in capsule endoscopy since 2001. The study reported early technical experience on DBE diagnostic and therapeutic maneuvers in multiple tertiary centers in the USA for 8 experienced endoscopists in 6 university or tertiary care centers. Of the 114 patients studied, 88 had previous CE and "the two tests correlated significantly ($p=0.004$)". The study includes data for 140 DBE procedures (with sedation): 86 upper DBE, 46 lower DBE. Data was notably consistent for the study parameters across all sites. Mean DBE procedure time was 103 minutes. Complications after DBE included abdominal pain at 24 hours-2, aspiration pneumonia-1, presumed asymptomatic microscopic perforation-1, mucosal tear-1 and stomal

perforation-1. Study conclusions: "DBE is time-consuming and does not reach the entire small intestine with initial endoscopist experience. Even with these limitations, DBE provides satisfactory results in half of these difficult cases."

Dr Lo notes that "According to current data, CE followed by DBE can provide a 1-2 punch in evaluation and management; CE can direct DBE—to gauge where to start, whether to do upper or lower DBE. This approach also allows many patients to be treated endoscopically after lesions are discovered, minimizing major surgery. For example, as I discussed in my presentation at the American College of Gastroenterology (ACG) meeting, this could probably limit surgery to 15-20% of all OGIB cases."



Maarten AJM Jacobs, MD, PhD, Small Bowel Diseases Unit, Department of Gastroenterology, Vrije University Medical Center, Amsterdam, the Netherlands

Dr Maarten AJM Jacobs (the

Netherlands) notes that "in our recent study¹⁰ published in the *American Journal of Gastroenterology*, we concluded: 'High detection rates of the causes of OGIB are feasible with CE and DBE. Although the detection rate of CE was superior (80%), our results indicate that the procedures are complementary; an initial diagnostic imaging employing CE might be followed by therapeutic / interventional DBE.' In my practice, I find this also applies to other indications as well, such as IBD and celiac disease."

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For an introduction to Satellite CE with the PillCam Platform, see GI insider Vol. 3 No. 2, 2005 available at www.givenimaging.com.¹⁻²



Lead investigator Jan-Magnus Kvamme, MD, Department of Gastroenterology, University Hospital of North Norway, Tromsø, Norway (Central PillCam Site)

"Northern Norway is characterized by a scattered population and significant distances between hospitals; travel can be difficult, especially in the winter. Collaboration between gastroenterologists works well in our region. In the study we found that remote [Satellite] capsule endoscopy is possible and has several advantages—this model is cost effective, well accepted by patients and also allows us to examine frail and elderly patients from the Satellite sites."



CE Practice Tips

Study Data on Satellite CE

This article is the next in our series "Building Satellite CE Practices." Study data on Satellite CE was presented at UEGW 2005. "Does Remote Capsule Endoscopy Reduce Costs?" focuses on economics and patient satisfaction for different CE practice models using the PillCam Platform; the abstract was published in Endoscopy/Gut³. This article highlights the data, benefits of the Satellite (Remote) CE model and other aspects of this study by Drs Jan-Magnus Kvamme, Ragnar Breckan, Ove Aronsen, Jon Florholmen, and Bjørn Wembstad from northern Norway.

Highlights

Aims of study

- Test the possibility of transferring capsule endoscopy data (from the PillCam SB video capsule) from Satellite Sites (equipped with a DataRecorder) to a Central PillCam Site (equipped with a complete Given Workstation) for analyzing the CE study.
- Evaluate patient tolerance and satisfaction regarding the procedure and different models.
- Assess economics/costs of different models.

Logistics aspects

- **Data transfer:** Mini-hard-disk [similar to DiskOnKey] transported from Satellite Sites by overnight airmail to the Central Site.
- **Central Site:** Department of Gastroenterology, University Hospital of North Norway, Tromsø.
- **Satellite Sites:** Department of Medicine, Nordland Hospital, Bodø and Department of Medicine, Hammerfest Hospital, Hammerfest, Norway.

Key datapoints

- **Indications** for CE with PillCam SB included bleeding (6/18), abdominal pain (6/18), evaluation of Crohn's disease (5/18) and diarrhea (1/18).
- **Patient tolerance** to the procedure was evaluated by a standardized questionnaire and compared to patients examined at the Central Site.



Presented at UEGW

Economic calculations:

- Total costs for 3 different models were estimated:
Model A: Satellite capsule endoscopy (2 Satellite Sites, 1 Central Site).
Model B: Transportation of all patients to the Central Site.
Model C: A complete workstation at all Sites.
- Based on an estimated estimate yearly number of CE examinations per Satellite Site.
- Capital equipment costs were assumed to be constant, with defined a life span, capital depreciation, etc.
- Recurring expenses common to all 3 models (ie, reading time and cost of capsule) were excluded from the economic analysis.

Conclusions

- Satellite capsule endoscopy (Model A) works well and appears to be more cost effective.
- All PillCam SB examinations (18) in the study were complete, successfully recorded, then transferred and analyzed.
- Patients' tolerance/satisfaction is high (score of 18.5 of 20); patient scores were equal at Central and Satellite Sites.

References

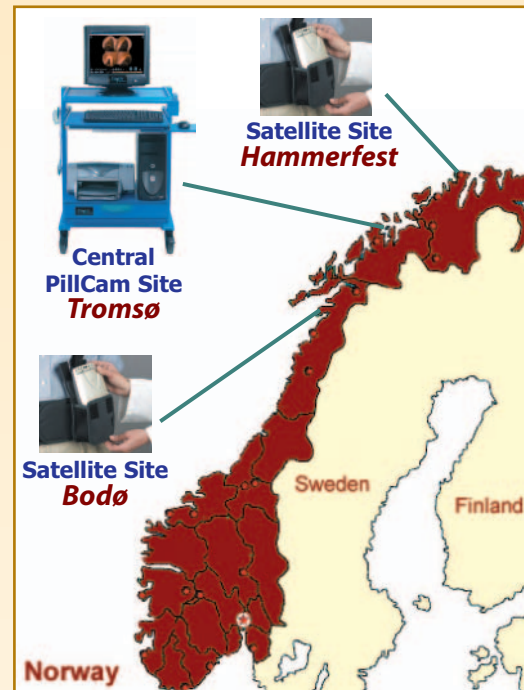
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Facing page:

Central PillCam Site Tromsø

Right: Northern lights over Satellite Site Hammerfest

Bottom: Midnight sun near Satellite Site Bodø



Study Model A: Satellite (Remote) CE
locations of sites are approximate



Ragnar Breckan, MD, Head of Gastroenterology, Department of Medicine, Nordland Hospital, Bodø, Norway (Satellite Site)

"In Bodø, we learned—as surely have many others—that CE with PillCam helps us make a precise diagnosis much faster than with ordinary means, and thus, spares the patients (and us) time, worrying and resources. Since our hospital does not have the staff to scrutinize the video (which Jan-Magnus in Tromsø does for us), the Satellite CE practice model works best for us."



Worldwide CE Community

Professional Excellence and Leadership

Regulatory Affairs Professionals Society Bestows Highest Honor on Shoshana Friedman

Shoshana (Shosh) Friedman, Given Imaging Senior Vice President, Regulatory and Clinical Affairs has received the Richard E. Greco Award, the highest honor bestowed by the Regulatory Affairs Professionals Society (RAPS), an educational/scientific organization. RAPS represents nearly 10,000 individuals worldwide in 45 countries who work in government, corporations, academia, research and nonprofit organizations.

The award recognizes outstanding leaders with significant contributions to the regulatory affairs profession and RAPS organization and who show personal involvement and commitment in their personal lives. Nominees for the award are judged on 1) Demonstrated contributions to regulatory affairs profession and health related arena 2) Positions of constructive service and leadership to RAPS, as well as 3) Exceptional service in community, civic, charitable organizations not related to employment. Ms. Friedman joined Given Imaging in 2002. She has been a member of the company's Advisory Board since June 1997 and led the clinical and regulatory activities for marketing authorization worldwide such as FDA clearance, CE-Mark, Canadian License and Australian Listing.



L-R: S. Albert Edwards, Chairman of RAPS Board of Directors, Shosh Friedman, Given Imaging Corporate Senior Vice President, Regulatory and Clinical Affairs and Sherry Keramidas, PhD, RAPS Executive Director

Japanese CE Image Atlas—Hot Off the Press

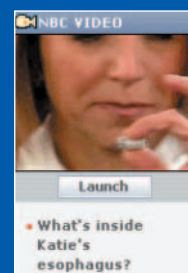


The Capsule Endoscopy Study Group (CESG) has just published the first Japanese CE Image Atlas. The result of several years of clinical research in Japan, it is based entirely on data and images from the PillCam SB video capsule, as well as global data and the ICCE Consensus. This Japanese-language image atlas joins the growing library of reference books in English, German and Spanish for the PillCam video capsule.

PillCam™ ESO Featured on USA National TV

"Today" show host Katie Couric ingested the PillCam ESO during a live broadcast on national TV in the USA. Ms Couric is known for undergoing a colonoscopy during a live broadcast to increase public awareness of the importance of regular screening (her husband died at an early age of colon cancer). Results of her PillCam ESO exam were analyzed by Felice Schnoll-Sussman, MD (USA).

See <http://www.msnbc.msn.com/id/10240327> and News at www.CapsuleEndoscopy.org. The ASGE issued a news release commending the coverage.



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