



ICCE · 2005 · MIAMI™

# CONFERENCE REPORT

# ICCE™

## 4th International Conference on CAPSULE ENDOSCOPY

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The International Conference on Capsule Endoscopy™ (ICCE) 2005, led by co-chairmen Drs Blair Lewis (USA), Jean-Francois Rey (France) and Ernest Seidman (Canada), reflected the latest developments in CE and clinical practice—Expanding Indications and Improving Outcomes. There were 526 participants from 37 countries; 10% were nurses with a central role in CE practices.

The ICCE, into its fourth year of sponsorship by Given Imaging, is the only international conference dedicated to capsule endoscopy. Presentations at ICCE are now cited at international GI meetings and referenced by professional societies as an established resource for clinical data on CE. This year's scientific program consisted of 118 abstracts focused on topics including inflammatory bowel disease (IBD), gastrointestinal bleeding, celiac disease, esophageal imaging, tumors, clinical practice, reimbursement and economics, preps and prokinetics, and clinical outcomes.<sup>1</sup>

A major goal of the ICCE 2005 was to establish a consensus on the use of Capsule Endoscopy in clinical practice. Participants worked together to establish consensus guidelines and algorithms to facilitate understanding among clinicians on the appropriate use of capsule endoscopy in the diagnostic work-up. This *ICCE Conference Report* is a summary of the consensus presentations and selected scientific talks.

The ICCE Learning Center was at overflow capacity throughout the general session. Physicians brought PillCam™ SB and PillCam™ ESO cases for review with colleagues for a variety of small bowel and esophageal diseases. Participants were also introduced to [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org), the new website inspired by the European Capsule Endoscopy Group (ECEG). The website's online resources include a database of CE publications, extensive image atlas, CE course schedules, discussion forums, case reports, etc. This dynamic resource collection is easily accessible at [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org).

Another unique aspect of ICCE 2005 was the wide variety of breakout groups. There was enthusiastic participation in diverse topics such as Global CE Reimbursement and Economics; Reading RAPID® Videos; Esophageal Imaging (Diagnosing Varices and GERD); Support Tools for CE Clubs; Nurses and Associates (Managing a CE Program). ICCE 2005 also provided a forum for regular meetings of CE professional special interest groups such as the ECEG and the American Society for Gastrointestinal Endoscopy (ASGE) CE special interest group (SIG). The growing ranks of both new and experienced CE specialists who convened at the ICCE demonstrated that the meeting is the leading forum for the latest developments in capsule endoscopy.

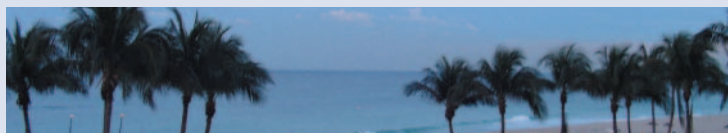
Conference co-chairmen and faculty are preparing the ICCE 2005 Consensus for publication this year as a special supplement to *Endoscopy*.

## Mark Your Calendar for ICCE 2006

The next International Conference on Capsule Endoscopy will be March 4-7, 2006 in Florida

E-mail [icce@givenimaging.com](mailto:icce@givenimaging.com) to receive future updates on the conference

The entire *Program & Abstracts of the 4th International Conference on Capsule Endoscopy* book can be downloaded from [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org) and [www.givenimaging.com](http://www.givenimaging.com)



# Inflammatory Bowel Disease (IBD)

The ICCE 2005 consensus on capsule endoscopy for inflammatory bowel disease (IBD) covers data for Crohn's disease—for both **suspected Crohn's disease** (to make initial diagnosis) and monitoring **known Crohn's disease** (to evaluate therapy and determine possible relapse)—as well as for **indeterminate colitis**. Studies presented at ICCE all noted **changes in outcomes for IBD after CE**. According to K.F. Bruin et al (Netherlands) "The finding of active disease always led to a change in patient management."<sup>1</sup>

## CONSENSUS SUMMARY<sup>2</sup>

### CE is

- More sensitive for assessing mucosal lesions than any other small bowel imaging technique
- Useful in patients with suspected Crohn's disease and negative endoscopic evaluations

### CE can be of value to identify and/or evaluate

- Small bowel mucosal lesions not seen on any other imaging modality
- Indeterminate colitis
- Unexplained symptoms of patients with known IBD

### CE may have a unique role to

- Assess mucosal healing after medical therapy
- Assess for early post-operative recurrence to guide therapy
- Serve as a subclinical marker in asymptomatic family members to teach us about the natural history of IBD

Though small bowel series is neither predictive nor protective, the Given® patency capsule\* can offer a potential solution when strictures are suspected.<sup>4,5</sup>

## MUCOSAL HEALING IN SMALL BOWEL CROHN'S DISEASE FOLLOWING THERAPY WITH INFLIXIMAB. ASSESSMENT USING THE CROHN'S DISEASE CAPSULE ENDOSCOPIC INDEX

Henry Debinski, Cabrini Hospital, Melbourne, Australia

Presented by H. Debinski, this study systematically assessed mucosal healing in 23 patients with an established diagnosis of small bowel Crohn's disease. Patients were screened using the Given patency capsule and PillCam SB: 10 were excluded; 13 patients with clinically-active disease (documented at CE) received 5 mg/kg of infliximab intravenously at weeks 0 and 6; previously undetected lesions were found in the proximal small bowel in 50% of patients at the first CE. At weeks 8 - 10 patients underwent a second CE study to assess mucosal healing. CE was able to demonstrate complete mucosal healing in 46% of the patients. Infliximab is effective in inducing clinical remission in small bowel Crohn's disease as measured by clinical outcomes, clinical markers such as the Crohn's disease Activity Index (CDAI) and the IBD Quality of Life Assessment and a new Crohn's Disease Capsule Endoscopic Index ("The Lewis Index").

## CAPSULE ENDOSCOPY: A VALUABLE HELP FOR THE DIFFERENTIAL DIAGNOSIS OF INDETERMINATE COLITIS?

Miguel Mascarenhas-Saraiva, Santo Antonio Hospital, Porto, Portugal

M. Mascarenhas-Saraiva presented 27 patients classified as having indeterminate colitis (IC), when evidence of chronic inflammation (endoscopy and histology) in the colon failed diagnostic criteria for ulcerative colitis (UC) and Crohn's disease (CD). Conventional work-up (upper and lower endoscopy, SBFT) was carried out in all patients prior to CE. Outcomes classifications: Diagnostic of CD for multiple ulcerations; Suspected CD for  $\leq 3$  ulcerations; and non-specific or normal for normal CE or non-specific findings. Results: 29.6% of patients showed inflammatory mucosal alterations in the small bowel: 22% diagnostic findings of Crohn's disease, 7.4% with suspected Crohn's disease. CE was normal or showed non-specific findings in the remaining patients. Conclusion: in patients without stenosis, capsule endoscopy is a safe and valuable tool in differential diagnosis of IC.

## PillCam™ SB Images Crohn's Disease



*Distal Ileal Crohn's disease ulcerations with active bleeding (top). Same patient after infliximab therapy (left): mucosal healing was visible throughout the small bowel*

*Courtesy of Henry Debinski, Cabrini Hospital, Melbourne, Australia*



*Pediatric Crohn's disease jejunal ulcerations*

*Courtesy of Colm O'Loughlin, Medical College of Wisconsin, Milwaukee, Wisconsin, USA*

\* The Given® patency system is not yet available in the USA; it received the CE Mark and is currently marketed in Europe, Australia and other countries.

# Celiac Disease

Participants at the ICCE 2005 discussed the clinical challenges of celiac disease, an immune-mediated disorder that primarily affects the GI tract in approximately 1% of the general population<sup>17</sup>. It is characterized by chronic inflammation of the small intestine mucosa that may result in atrophy of intestinal villi, malabsorption, and a variety of clinical manifestations, which may begin in either childhood or adult life.

According to C. Cellier, panel leader for the ICCE 2005 Consensus on Celiac Disease, this is just “the tip of the iceberg” since affected patients do not always present with classical symptoms of malabsorption. Celiac disease is recognized as being under-diagnosed and patients often have non-specific complaints.

## CONSENSUS SUMMARY<sup>18</sup>

### Background<sup>17</sup>: Diagnosing Celiac Disease

- Symptoms mimicking irritable bowel syndrome (IBS) such as diarrhea, bloating, abdominal pain as well as failure to thrive

### VIDEO CAPSULE ENDOSCOPY FOR THE DIAGNOSIS OF CELIAC DISEASE: PRELIMINARY DATA FROM A MULTI-CENTER INTERNATIONAL STUDY

**Roberto de Franchis, University of Milan, Milan, Italy**

R. de Franchis presented initial data from this multi-center, international study on CE and celiac disease. The first 25 consecutive patients who had positive serological tests for celiac disease showed 94.4% sensitivity and 85.7% specificity of capsule endoscopy in diagnosing celiac disease when compared to histology. R. de Franchis concluded that based on this preliminary data, CE appears to be equivalent to histology for detecting severe pathological findings in patients with suspected celiac diseases.

### EVALUATION OF CAPSULE ENDOSCOPY IN CELIAC DISEASE PATIENTS WITH ONGOING SYMPTOMS ON A GLUTEN-FREE DIET: FIRST RESULTS OF A PROSPECTIVE BLINDED EUROPEAN MULTI-CENTER TRIAL

**Norbert Krauss, University of Erlangen, Erlangen, Germany**

In the presentation by N. Krauss of the first 59 patients studied, capsule endoscopy showed good correlation with prior histological findings as well as additional findings beyond the reach of conventional endoscopy, including gastrointestinal tumors in 2 of 43 patients (5.6%).

[Editor's note: this is consistent with recent data on prevalence of small bowel tumor findings in patients after capsule endoscopy. See page 4.]

- Anemia: iron, folate or B-12 deficiency
- Elevated transaminases
- > 60 years old (20%)
- Patients with celiac disease may also have diabetes, anemia, osteoporosis, neurological problems, malignancies, and show behavioral changes
- Family members may also be positive for celiac disease

### Celiac Disease Indications for CE

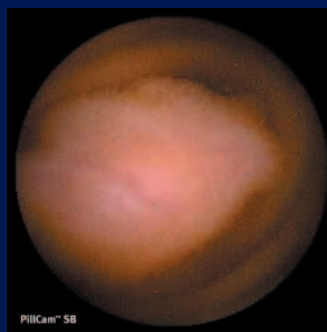
- For positive serology in patients unwilling or unable to undergo upper GI endoscopy
- For positive serology in patients with negative biopsy to visualize patchy, difficult-to-diagnose disease
- For alarm symptoms in patients with known celiac disease: obstruction, weight loss, bleeding, pain, fever

## PillCam™ SB Images Celiac Disease



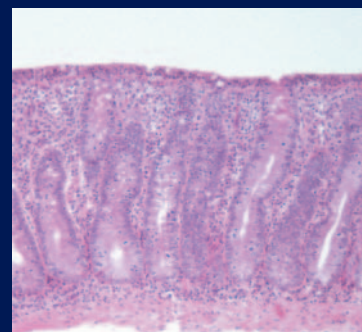
**Various degrees of villous atrophy: variable scalloping, fissuring and flattening of mucosa**

*Courtesy of Roberto de Franchis, University of Milan, Milan, Italy*



**Intussusception**

*Courtesy of Norbert Krauss, University of Erlangen, Erlangen, Germany*



**Histology: Total villous atrophy with an increased number of intraepithelial lymphocytes consistent with celiac disease**

*Courtesy of Christophe Cellier, University of Paris, Paris, France*

# GI Bleeding, Anemia & Small Bowel Tumors

“When we look at American data, between 2 and 5% of the population at any one time will have **anemia**. That means if we take an urban population of approximately one million, there will be about 20,000 patients with iron deficiency anemia at any one time.

**Should all of these patients have capsule endoscopy?** As we know a priori, these patients will probably have an endoscopy or colonoscopy beforehand. About 50% of patients who are undergoing that prior workup will have no diagnosis at the end. We should therefore be convinced that capsule endoscopy offers a very important diagnostic tool.

**How do we approach iron deficiency anemia?** I don’t make any differentiation on the basis of the age of the patients. The critically important question as to whether that patient has bleeding. This is one of the key messages, that not only do we see lesions which are clinically important in terms of bleeding, but they are critically important in terms of patient outcome—and that quite likely **capsule endoscopy will shorten considerably the time-to-diagnosis in the unfortunate group of patients with small bowel tumors.**

There are other [small bowel] diseases which present with iron deficiency anemia:

- Patients with **Crohn’s disease** also present clearly with obscure GI bleeding.
- **NSAID damage** is predominantly a small bowel disease... NSAID anemia may in fact be due to small bowel blood loss.
- Anemia can frequently complicate **celiac disease**.
- Clearly other disease processes contribute to the spectrum of recurrent bleeding.”<sup>24</sup>

John Morris, Glasgow Royal Infirmary, Glasgow, UK

Participants at the ICCE 2005 discussed the correlation between **GI bleeding (GIB)**, particularly obscure GIB (OGIB), **iron deficiency anemia (IDA)** and **small bowel tumors**. Lively discussion followed the general session interactive voting results revealing that **anemia is the most common presenting condition in approximately 80% of GI practices.**

## CONSENSUS SUMMARY<sup>25</sup>

- **Key advantages of CE include:** ability to review and share images; patient preference; safety profile; ability to conduct in variety of settings; clarity of image comparable to other diagnostic methods; ability to image entire small bowel

“We have been taught that the most common presentation of a small bowel tumor is ‘intestinal obstruction’. I think we’ve realized that there is a paradigm shift and that technology has driven us to understand that the primary symptom is anemia and GI blood loss. In patients with small bowel tumors, the most common presentation is anemia and occult GI bleeding... they occur in both benign and malignant [tumors], probably more in malignant because of mucosal destruction, weight loss and obstruction are late symptoms...”

## Diagnosis and Improved Outcomes after Capsule Endoscopy with PillCam



**Acute active bleeding site in ileum.** Prior to CE, patient had anemia, required transfusions and had negative gastroscopy, colonoscopy and push enteroscopy.

Courtesy of Norbert Krauss, University of Erlangen, Erlangen, Germany



**Small bowel tumor site with obscure GI bleeding site in proximal jejunum** revealed only by CE.

Patient had 3-year history of bleeding with persistent iron deficiency anemia; extensive negative work-up failed to identify bleeding source; curative surgery was performed after CE.

Courtesy of Marco Pennazio, S.Giovanni Antica Sede Hospital, Turin, Italy



**Jejunal carcinoid tumor.** Prior to CE, patient had anemia, negative work-up, and acute bleeding requiring transfusion. Following resection, the tumor was pathohistologically found to be malignant.

Courtesy of Ziva Mrevlje, University Medical Center Ljubljana, Slovenia

“CE gave the only definitive information that led to therapeutic removal of the carcinoid. If CE had been performed earlier in the diagnostic workup, it would have reduced time to diagnosis, costs and patient discomfort.”

- CE should be part of the initial investigation in patients with obscure bleeding for whom there is no suspected obstruction.
- In these patients, the early use of CE would lead to earlier diagnoses and reduced costs

**Outcomes of Importance**

- Bleeding stops/anemia resolves
  - Less need for transfusions, fewer hospitalizations
- Reduced diagnostic cost and utilization
- Reduced treatment cost and utilization
- Patient satisfaction and quality of life (QoL)
- Improved outcome of earlier-diagnosed tumors in the small bowel

The PillCam [video capsule] detected these small bowel tumors after a plethora of other diagnostic tests, approximately five per patient.<sup>26</sup>

We've learned that:

- The majority of small bowel tumors are malignant, approximately two-thirds.
- We find them late [due to our current] paradigm, which is doing multiple tests before we apply the [video] capsule.<sup>27</sup>

Jamie Barkin, University of Miami, Miami, Florida, USA

**Latest Clinical Data on Small Bowel Tumors**

Recent CE studies<sup>28,29,30,31,32,33</sup> confirm that the prevalence and malignancy rates for small bowel tumors are much higher than previously reported:

- Clinical data from major international CE studies covering 1,551 patients
- Prevalence of small bowel tumors 5.4%–8.9% [weighted average 7.4% based on patients/study]
- Malignancy rate: approximately two-thirds

**DIAGNOSIS AND OUTCOME OF SMALL BOWEL TUMORS FOUND BY CAPSULE ENDOSCOPY - A THREE-CENTRE AUSTRALIAN EXPERIENCE**

Warwick S. Selby, University of Sydney, Sydney, Australia

This presentation by W. Selby covered results of the first multi-center study on CE and outcomes for small bowel tumors (SBT). A series of 416 CE studies detected 26 patients with SBT; the primary indication for CE was OGIB (81%). Twenty-seven tumors were identified in 26 patients. Mean duration of follow-up was 507 days (116-1044). Most patients had no symptoms suggestive of small bowel obstruction and had undergone gastroscopy and colonoscopy prior to CE. Prior radiology, most of which was normal, had been performed in 23 of 26 patients and enteroscopy in 7. Histology was available in 25 of 26 patients. Prevalence of tumors was 6.5% and malignancy rate was 69%: Tumors were resected in 23 (88%) patients, (1 patient declined surgery) and 18 tumors were found malignant; resection was considered potentially curative in 9 of 23 patients (39%).

W. Selby concluded: Small bowel tumors are a significant finding at CE and are often unsuspected, not being found by other methods. Detection of a tumor using CE often alters management and improves outcome. Even in malignant lesions, treatment is potentially curative.

“This is certainly something that drives us to do capsule endoscopy, and it’s not just the malignant versus the benign, but it’s the neoplastic versus the non-neoplastic. It’s actually, [when] your numbers get put together that the neoplastic is much higher, even better than two-thirds, and so people have to be aware of that, because you are preventing cancer, it’s just like doing colonoscopy, you are preventing cancer, not even diagnosing early cancer.”

Blair S. Lewis, Mount Sinai Medical Center, New York, USA

m™ SB



**Adenocarcinoma. Patient presented with 10 months iron deficiency anemia; normal endoscopy, colonoscopy and small bowel follow-through. After CE, tumor resected but metastases found at surgery.**

Courtesy of Warwick Selby, University of Sydney, Sydney, Australia

# Esophagus

Panel leaders at ICCE 2005 remarked on the “excellent initial clinical data” for **esophageal capsule endoscopy (ECE) with the PillCam™ ESO**, a twin-camera video capsule that became available worldwide in 2004. ECE signifies a new approach to esophageal diagnostics that is simple, easy to use and patient friendly, with important applications as a screening tool. Results of interactive voting during the ICCE 2005 general session indicate that 50% of physicians currently scope chronic reflux (GERD) patients in advance of therapy, and 50% perform EGD when therapy fails. In view of this clinical practice, conference participants discussed the role of ECE as a patient-friendly, screening alternative. V. K. Sharma, panel leader of the ICCE 2005 Consensus on Esophagus also noted the economic burden of reflux, which is associated with Barrett’s esophagus and adenocarcinoma, which has tripled in the last 30 years.

In addition to **Barrett’s esophagus**, there is now important initial data on ECE with the **PillCam™ ESO video capsule for esophageal varices**, with a potential role in screening and surveillance of varices in patients with chronic liver disease, chronic Hep b, chronic Hep c, and cirrhosis.

## CONSENSUS SUMMARY<sup>42</sup>

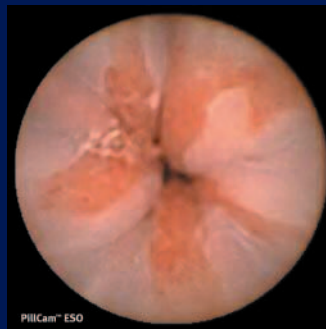
### Barrett’s Esophagus

- Patients with chronic GERD symptoms can undergo ECE; those with suspected Barrett’s esophagus visualized at ECE, should undergo EGD
- ECE is a non-invasive alternative to EGD for imaging the esophagus—current data: Sensitivity: 90%–97%; specificity approaches 100%
- Appears to be cost-effective for screening

### Esophageal Varices

- Esophageal varices (EV) are a serious consequence of portal hypertension (PHT). In patients with cirrhosis, the incidence of EV increases 5% per year and the rate of progression from small to large varices is 5%–10%
- Increasing size of varices is associated with increased wall tension leading to rupture and bleeding
- Mortality rate from variceal bleeding is approximately 20%
- AASLD/UK guidelines recommend endoscopic screening of patients with cirrhosis for varices, and treatment of patients with medium/large varices to prevent bleeding
- Recommended endoscopic screening intervals are 1–3 years, depending on presence/absence of varices and whether patient has compensated/decompensated liver disease
- Endoscopic surveillance is performed in patients after obliteration of varices
- These recommendations/practices represent a potentially large endoscopic burden
- This patient population could benefit from a non-invasive diagnostic test that does not require sedation
- Patient acceptance of an alternative screening modality could improve adherence to recommendations and appropriate treatment after risk stratification
- Potentially a role in screening and surveillance of varices in patients with chronic liver disease

## PillCam™ ESO Images Esophageal Diseases



**Barrett’s esophagus**

Courtesy of  
A. Rami Eliakim,  
Rambam Medical Center,  
Haifa, Israel



**Barrett’s esophagus islands**

Courtesy of  
Virender K. Sharma,  
Mayo Clinic, Scottsdale,  
Arizona, USA



**Esophageal varices**

Courtesy of Glenn Eisen, Oregon Health and Science University, Portland, Oregon, USA



**Portal hypertensive gastropathy; note swollen mucosa**

## EVALUATION OF ESOPHAGEAL VARICES BY PILLCAM ESO AS COMPARED TO UPPER ENDOSCOPY: PRELIMINARY RESULTS OF INTERNATIONAL MULTI-CENTER TRIAL

Glenn Eisen, Oregon Health and Science University, Portland, Oregon, USA

Early results presented by G. Eisen of the first international multi-center trial compared esophageal capsule endoscopy (ECE) to traditional upper endoscopy (EGD) to screen 32 patients with end-stage liver disease for esophageal varices (EV). ECE with the Pillcam ESO was performed prior to EGD, and EGD was performed within 48 hours, but generally the same day. Sensitivity value for ECE was 100%, specificity 89%, PPV 96% and NPV 100%. There were no complications. G. Eisen concluded that ECE may provide a safe, well-tolerated alternative to upper endoscopy in the detection of esophageal varices and portal hypertension. Additionally, utilization of ECE could allow more directed use of upper endoscopy for patients requiring variceal obliteration.

# Preps & Prokinetics

At ICCE 2005 there was much discussion in the working groups and general session on bowel preparation (preps) and prokinetics. For preps, the study by A. Andrews et al (USA) was cited by co-chairman B. Lewis as “Distinguished Poster, Best of ICCE 2005” as exemplary of the study-design needed, with cross-over design on the same patients with no prep and then prep two weeks later. For prokinetics, several new studies were presented on the effect of patient-positioning maneuvers, also known as postural tricks, for motility.

These continue to be controversial topics—at the ICCE as well as in actual clinical practice. Clinical studies to date have yielded varied results and include factors that prevent data from being combined and analyzed collectively. As a result, the ICCE 2005 Consensus on preps and prokinetics resulted in a summary of definitions, questions and criteria for future multi-national studies to pool more conclusive data.

## CONSENSUS SUMMARY<sup>47</sup>

### Definitions

- **Bowel preparations (Preps):**  
medications for cleansing the small bowel
- **Prokinetic agents and maneuvers (Prokinetics):**  
methods for accelerating gastric emptying and/or small bowel transit times, thus improving the proportion of cases in which the colon is reached

### Clinical Challenges for Small Bowel Imaging with Capsule Endoscopy

- Presence of dark/opaque intestinal contents or bubbles in the (distal) small bowel, which may impair visualization of mucosa
- Slow gastric emptying and/or small bowel transit, thus causing incomplete small bowel imaging

### Questions

Do preps/prokinetics improve the quality of small bowel cleanliness?	Probably yes
Do they improve GTT/SBTT/Completeness of examination?	Possibly yes
Do postural tricks shorten GTT?	Possibly yes
Do they improve the diagnostic yield?	Unknown
Do prokinetics increase the miss rate?	Unknown
Do preps/prokinetics cause side effects?	Unknown
Is acceptance of the patients decreased by preps/prokinetics?	Unknown

### Conclusions

- It is not clear if preps/prokinetics improve the diagnostic yield in capsule endoscopy
- It is likely that prokinetics do improve the completeness of examination
- Published literature is not conclusive, therefore further studies are needed

The entire *Program & Abstracts of the 4<sup>th</sup> International Conference on Capsule Endoscopy* book can be downloaded from [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org) and [www.givenimaging.com](http://www.givenimaging.com)

Each year, the ICCE sparks many new research efforts in capsule endoscopy. The ICCE 2005 Consensus groups have defined criteria for many new and exciting studies.

### RESEARCH TOPICS INCLUDE:

**IBD, GI Bleeding, Anemia, Small Bowel Tumors, Esophageal Diseases, Celiac Disease, and Preps and Prokinetics**

**For more information on new clinical studies on CE in your area of expertise:**

[clinical@givenimaging.com](mailto:clinical@givenimaging.com)

Department of Regulatory and Medical Affairs, Given Imaging

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