



# 1ST INTERNATIONAL WORKSHOP ON COLON CAPSULE ENDOSCOPY

## Workshop Report

Vol. 1

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Now in its seventh year, the International Conference on Capsule Endoscopy™ (ICCE™) remains the preeminent symposium for capsule endoscopy (CE). As a result of physician interest, a dedicated, interactive international workshop was held for the first time to focus on the emerging modality of colon capsule endoscopy. This publication, the *ICCE Workshop Report Vol. 1*, is a summary of selected presentations and scientific talks from the workshop.



The 1st ICCE Workshop on Colon Capsule Endoscopy convened in Berlin, Germany and was co-chaired by G. Costamagna (Italy) and W. Schmiegel (Germany). With joint sponsorship by Given Imaging and Fujinon, the ICCE is still the only international congress focusing entirely on capsule endoscopy. Over 200 physicians and medical professionals from 32 countries came to this year's dedicated workshop to learn more about colon capsule endoscopy (CCE) and PillCam® COLON.

Presentations included recent scientific data on using PillCam COLON to evaluate colonic mucosa. Topics included colorectal cancer, colon polyps, colonic inflammatory lesions and ulcerative colitis, scoring indexes for characterizing colonic mucosal damage and healing, and regimens (prep and procedures) for CCE. There were lively discussions on economics and optimizing the utility of CCE in current clinical practice and potential screening applications. Several sessions also emphasized the ongoing impact of the updated ICCE Consensus, published in *Endoscopy*, and CE for the esophagus and small bowel.

Also at the Berlin meeting, ICCE Learning Center activities included hands-on demonstrations of the Given Imaging PillCam Platform's new RAPID® software features for image-enhancement and RAPID Access for CE in a networked environment; as well as the latest techniques for double-balloon endoscopy (DBE) from Fujinon. This year's European Capsule Endoscopy Group (ECEG) Research Grants were awarded at the Berlin meeting (see page 8).

For more information on the ICCE, visit the website [www.ICCE.info](http://www.ICCE.info) for summaries (including issues of the *ICCE Conference Report*), consensus material, and an abstract archive. The website is also accessible from the [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org) homepage.



Visit [www.ICCE.info](http://www.ICCE.info)

for consensus material and archives of abstracts and ICCE Reports.

To receive updates on ICCE events, click the Contact Us link.

\*PillCam COLON has received a CE Mark, but is not cleared for marketing or available for commercial distribution in the USA.

# Detecting Colonic Polyps and Cancer

The European multicenter study data presented by J. Devière (Belgium) at the 1st International Workshop on Colon Capsule Endoscopy represents the largest clinical study to date on CCE. Principal investigator of the PillCam COLON feasibility and pilot studies R. Eliakim (Israel) introduced Devière's lecture and the scientific sessions with a quote from the American Gastrological Association (AGA) Future Trends Report, *Gastroenterology* (2006; 131:1287-1312):

*"Wireless capsule endoscopy represents one of the most significant and exciting breakthroughs in endoscopic technology in recent years. The capsule has clearly revolutionized small bowel imaging... A version for imaging the colon is under study and, if proven effective, will clearly represent a second revolution in bowel imaging."*

This potential for CCE as an effective tool was reinforced by C. Hassan (Italy) in his presentation of economics modeling data (on page 6).

## PillCam COLON Capsule Endoscopy Compared to Colonoscopy in Detection of Colon Polyps and Cancers: Analysis of a Prospective Multicenter European Study

J. Devière, Hôpital Erasme, Brussels, Belgium

Devière presented an analysis of a multicenter European study of detecting colon polyps and cancers using CCE with the PillCam COLON compared to colonoscopy. Final analysis covered prospective data from 320 patients from 8 sites in Belgium, France, Germany, Italy, Spain, and the UK. He noted that in pilot studies, CCE with PillCam COLON has been shown to be safe and able to visualize colon polyps and cancers. This study was conducted with the primary objective to assess the accuracy of PillCam COLON to colonoscopy.

Patients included in this study were known to have (age  $\geq 18$  years) or were suspected of having (age  $\geq 50$  years) colonic disease and were referred for colonoscopy. Patients received a standard PEG-based colon prep and ingested the PillCam COLON video capsule in the morning. The PillCam COLON procedure / regimen also included a prokinetic medication and additional small doses of laxatives. No sedation, tube insertion, or air insufflation was required. Independent physicians performed CCE interpretation and colonoscopy (gold standard) after PillCam COLON video capsule excretion. Review of PillCam COLON and colonoscopy studies was by double-blinded review process.

**Results:** A total of 328 patients (mean age: 59 years; range: 22-84) were enrolled; 320 were included in the final analysis. There was 1 severe adverse event related to colonoscopy. PillCam COLON video capsules were excreted within 10 hours post-ingestion in 93% of the patients and within 6 hours in 69%. Quality of colon cleansing was evaluated according to a 4-point scale; 72% of the patients had colon cleansing levels of Good-to-Excellent. Accuracy parameters for polyp detection with PillCam COLON compared to colonoscopy were particularly encouraging for Good-to-Excellent colon cleansing levels. See Tables 1-3.

**Conclusions:** CCE with PillCam COLON is a new minimally-invasive and safe technology for visualizing the colon. PillCam COLON shows encouraging accuracy for detecting polyps compared to colonoscopy and may be an alternative for patients who cannot or are unwilling to undergo colonoscopy.

**Table 1. Reasons for Referral**

	Age 18-49 y	Age $\geq 50$ y	All patients
Patients known to have colonic disease	57	58	115 (35%)
Patients suspected of having colonic disease	7	206	213 (65%)
All patients	64 (19.5%)	264 (80.5%)	328

**Table 2. PillCam COLON Findings and Accuracy (Compared to Colonoscopy)**

Findings	No. of Patients	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
In patients with Good-to-Excellent cleansing levels (72% of all patients)					
Any size polyps	149	76%	80%	88%	63%
Significant finding*	93	75%	83%	75%	83%
Polyp $\geq 6$	59	75%	84%	62%	90%
Polyp $\geq 10$	33	76%	98%	89%	96%
In all patients (n=320)					
Any size polyps	212	72%	78%	86%	59%
Significant finding*	134	66%	82%	72%	77%
Polyp $\geq 6$	87	64%	84%	60%	86%
Polyp $\geq 10$	50	60%	98%	83%	93%

\* At least 1 polyp  $\geq 6$  mm or  $\geq 3$  polyps of any size.

## References

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# Colon Capsule Endoscopy Regimen

The current baseline regimen for CE with PillCam COLON is shown in Table 3. Several sessions at ICCE Berlin covered ongoing research on new prep and procedure variations (including day vs night procedures) in studies presented by S. Bar-Meir (Israel), T. Brechmann (Germany), C. Carretero (Spain), G. Costamagna (Italy), Z. Fireman (Israel), and M.

Philipper (Germany). Presentations by M. Delvaux (France) and H. Schulz (Germany) on PillCam COLON experience in regional studies also included variations of the base regimen in office-based, clinic-based, and hospital settings which evaluated daily workflow for CE of the colon.

**Table 3. Baseline Colon Prep and Procedure (Regimen Used in Multicenter European Study)**

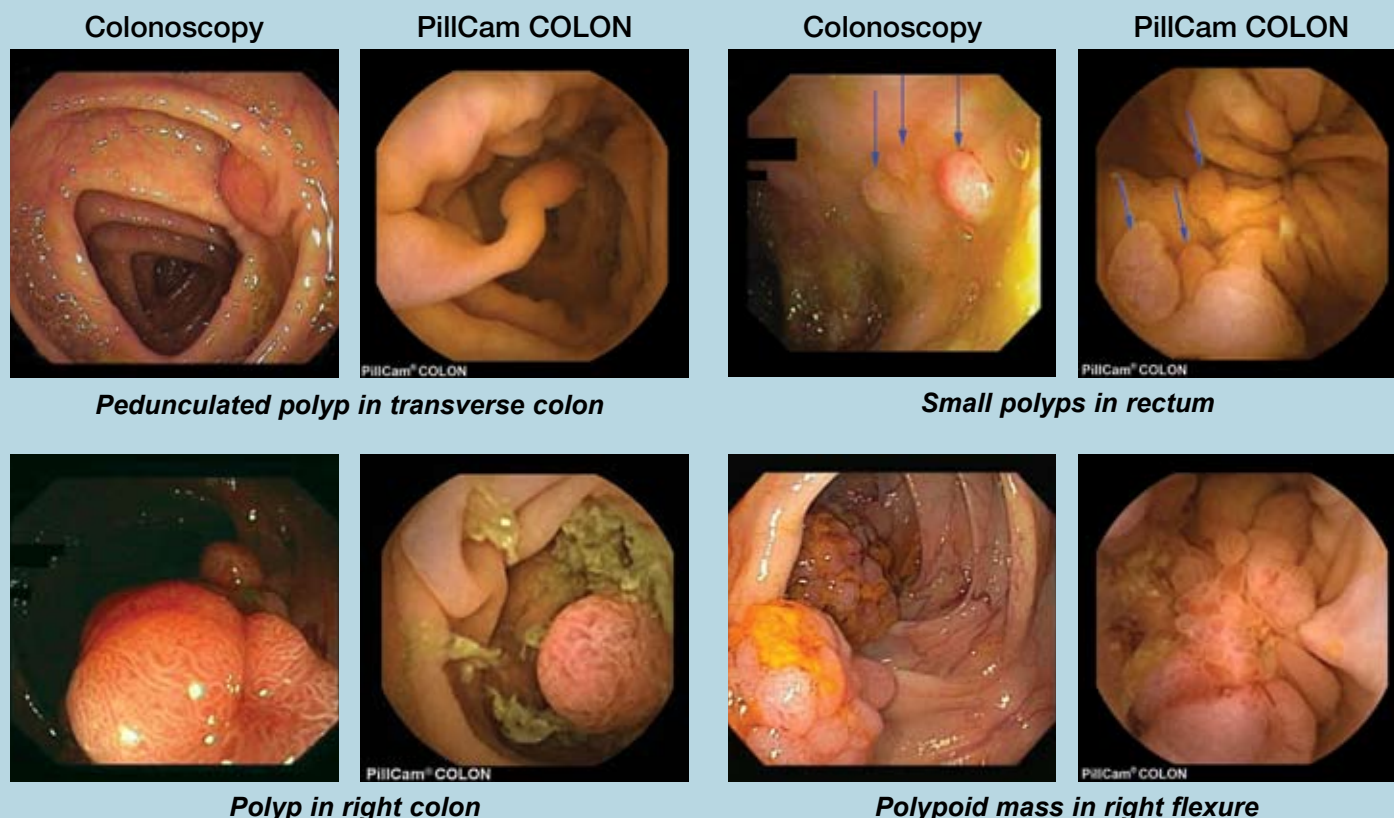
Schedule		Colon prep and procedure
Day before		Clear liquid diet all day (no breakfast) + 3 L Colopeg®
Exam day	6:00 – 7:00	1 L Colopeg
	7:45 – 8:00	20 mg Domperidone + (after 15 min) PillCam COLON ingestion
	10:00	*Booster I: 45 mL NaP
Only if needed	14:00	Booster II: 30 mL NaP
	16:30	10 mg Bisacodyl suppository

\*Pending exit of PillCam COLON from the stomach (verified via RAPID Real-Time device)

93% of patients in the European multicenter study completed the PillCam COLON exam and excreted the capsule within 10 hrs post-ingestion; 69% completed the PillCam COLON exam without need for Booster II and within 6 hrs.

## Detecting Colonic Polyps and Cancer

*Note the different views of colon mucosa: With insufflation in colonoscopy, polyps can appear flattened; PillCam COLON images the mucosa through clear fluid without using insufflation.*



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# IBD and Mucosal Healing

The potential role of CCE in evaluating colonic inflammatory bowel disease and mucosal healing was an important topic at the workshop. The presentation by J. J. Y. Sung (Hong Kong) of interim clinical results of the first pilot study using PillCam COLON for evaluating ulcerative colitis was received with enthusiasm. J. F. Colombel (Belgium) discussed the various needs for evaluating mucosal injury and healing in ileocolonic Crohn's disease. During question-and-answer sessions, panel members and the audience discussed applying existing tools such as the Lewis Score (integrated in RAPID 5) for characterizing colonic lesions, as well as other areas of future study.

## Evaluation of PillCam COLON Capsule Endoscopy in the Assessment of Colonic Inflammatory Lesions in Ulcerative Colitis: An Interim Analysis

J. J. Y. Sung, Chinese University of Hong Kong, Hong Kong, China

Introducing this interim analysis, Sung emphasized that active ulcerative colitis (UC) is associated with an increased risk of colorectal dysplasia and cancer. Treatment of UC should be closely monitored and follow the level of severity of colonic inflammation. There is also a need for surveillance of CRC especially in patients with extensive disease for prolonged periods. In previous studies, CCE with PillCam COLON has been shown safe and able to demonstrate colon polyps and cancer. The primary objective of this ongoing pilot study was to evaluate the accuracy of capsule endoscopy with the PillCam COLON in monitoring colonic inflammation and UC in comparison to colonoscopy.

Inclusion criteria were patients 18-70 years old referred to colonoscopy for suspected or known inflammatory lesions or other colonic disease. Patients had a traditional PEG colon prep and ingested the video capsule in the morning. The PillCam COLON procedure was designed to enhance capsule propulsion and maintain clean colon during the procedure. No sedation, intubation, or insufflation was required. Following capsule excretion, colonoscopy (gold standard) was performed the same day. Independent physicians performed PillCam COLON and colonoscopy evaluations. UC disease was activity classified into 1 of 3 groups (according to findings):

1. **Normal or not related to UC** (polyps, vascular lesions, diverticulitis)
2. **Non-active UC** (pseudopolyps, scarring, mosaic pattern, cobblestoning)
3. **Active UC** (ulcer, erythema, erosions, edema, exudates, proctitis)

**Results:** 42 patients (mean age: 48 years; range: 27-68) were enrolled; 40 included in the interim analysis. No adverse events were related to the PillCam COLON video capsule. Capsules were excreted within 8:30 hours post-ingestion in 97.5% of the patients and within 5:30 hours in 60%. Colonoscopy detected active UC in 22 patients, and the accuracy of PillCam COLON compared to colonoscopy was 77% sensitivity, 78% specificity, 81% PPV, and 74% NPV. The agreement level (kappa) between

PillCam COLON and colonoscopy of classifying the UC disease into 1 of the 3 groups was 0.6. See Tables 4 and 5.

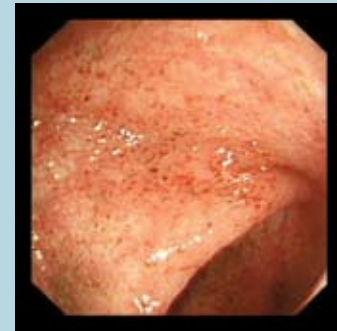
**Conclusions:** CCE with PillCam COLON is a safe and well-tolerated procedure. It has encouraging accuracy for detection of active UC and substantial agreement with colonoscopy. The high acceptability of PillCam COLON may increase adherence to monitoring activities in UC patients.

Areas of future research:

- Development of a scoring system for the assessment of the severity of colonic inflammation in UC by using PillCam COLON in order to tailor individual treatment
- Use of PillCam to define the extent of disease involvement in UC using PillCam COLON
- Use of PillCam COLON in surveillance for cancer

## Classification of

### Colonoscopy (left column)



Diffuse



Pseudopolyps; flattened insufflation at

Table 4. Reasons for Referral

No. of Patients	Abdominal Pain	Ulcerative Colitis	Rectal Bleeding
10 (25%)	✓		
23 (57%)		✓	
4 (10%)			✓
2 (5%)		✓	✓
1 (3%)	✓	✓	✓

Table 5. Classification of UC Activity (Per Patient Analysis)

		Colonoscopy		
		Normal / not related to UC	Non-active UC	Active UC
PillCam COLON	Normal / not related to UC	12 (80%)	0	4
	Non-active UC	0	2 (67%)	1
	Active UC	3	1	17 (77%)

Substantial agreement between PillCam COLON and colonoscopy (kappa statistic = 0.6).

# Ulcerative Colitis Disease Activity

n) and PillCam COLON Views of UC



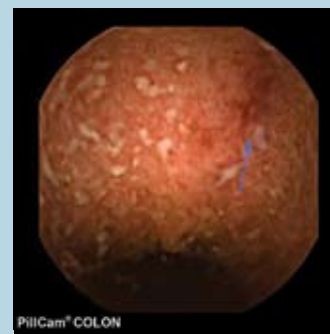
**erythema**



**Erosions**



**Erosions, edema, erythema**



**Severe erosions, edema, erythema**

Active UC



**appearance at left due to colonoscopy**



**Pseudopolyps**



**Mosaic pattern**

Non-Active UC

*J. J. Y. Sung, Chinese University of Hong Kong, Hong Kong, China*

Following is a case where colonoscopy was incomplete because of the presence of a sigmoid stricture while the PillCam COLON video capsule allowed a complete examination of the colon. CCE enabled detection of colonic polyps proximal to the sigmoid stricture that would have otherwise been missed; it was reliable in localizing the site of the findings (confirmed at repeat colonoscopy) both for polyps and colonic Crohn's

disease; it also provided accurate estimation of polyp size when compared to colonoscopy as a gold standard.

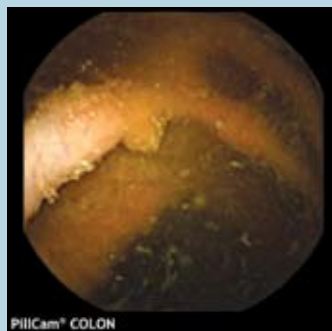
Furthermore, PillCam COLON findings guided therapy (medical treatment of colonic Crohn's disease and polypectomy) and improved patient management and outcomes. The patient is in good clinical condition after 18 months of follow-up.

## PillCam COLON Complements Incomplete Colonoscopy

Colonic polyps missed at incomplete colonoscopy



**Large sessile polyp > 10 mm suggestive of adenomatous polyp**



**Small sessile polyp < 6 mm suggestive of hyperplastic lesion**

Colonic Crohn's disease in same patient



**Erosions, narrowing, and ulcer in left colon**



**Hyperemia, ulcerations in rectum**

*C. Spada, Catholic University and European Endoscopy Training Center, Rome, Italy*

# Economics of CRC Screening

At the ICCE Workshop on Colon Capsule Endoscopy a number of presentations covered different aspects of CRC screening—especially the potential of CCE with PillCam COLON to improve patient compliance, and subsequently improve outcomes. W. Schmiegel (Germany) discussed indications for screening and surveillance of high-risk groups such as patients with a family history of CRC and hereditary nonpolyposis colon cancer (HNPCC), familial adenomatous polyposis (FAP), and Peutz-Jeghers syndrome (PJS).

For the first time at ICCE, an economic modeling study was presented on CCE in the average-risk, general population that fails to comply with current CRC screening guidelines; C. Hassan (Italy) concluded that PillCam COLON may be a cost-effective approach to preventing CRC in this general patient population. This study was also published in the May issue of *Endoscopy*.

## Cost-effectiveness of Colorectal Cancer Screening with Capsule Endoscopy

C. Hassan, Nuovo Regina Margherita Hospital, Rome, Italy

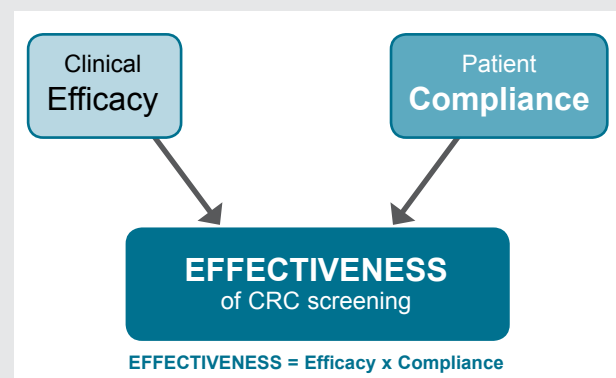
Hassan pointed out that CRC screening rates remain disappointingly low when compared to the success of other cancer screening programs. Colorectal cancers are preventable through early detection, and this minimally-invasive option may aid in significantly reducing the more than 212,000 annual deaths in Europe due to colorectal cancer. The aim of this analysis was to provide a model to assess the cost and effectiveness of population-based screening for CRC using capsule endoscopy compared with that of a standard colonoscopy screening program.

A Markov mathematical model was constructed to simulate a comparison of CRC screening scenarios comparing PillCam COLON with standard colonoscopy. Model parameters were varied to simulate alterations in cost, thresholds for treatments, sensitivities and specificities, and screening adherence rates. Through pooled analyses, it was determined that a threshold  $\geq 6$  mm for polypectomy referral substantially reduced costs while only minimally impacting efficacy.

*[Editor's Note: Markov models are useful when a decision problem involves risk that is continuous over time, when the timing of events is important, and when important events may happen more than once.]*

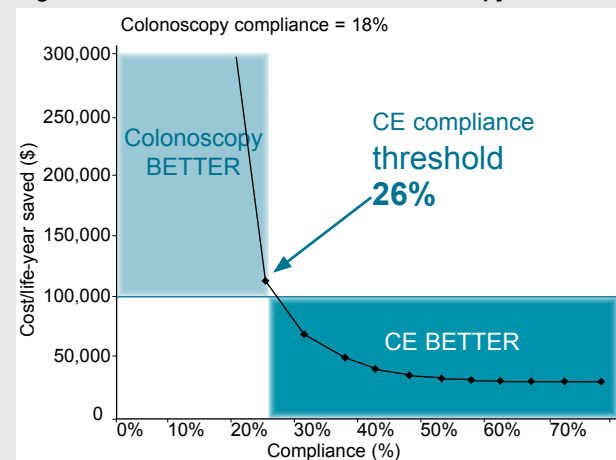
**Conclusions:** Cost-effectiveness of CRC screening using PillCam COLON will mainly depend on its ability to improve compliance in the general population. The very low adherence achieved by colonoscopy prompts an urgent need for minimally-invasive alternatives, such as capsule endoscopy. (See Figures 1 and 2.) The impact of compliance on the effectiveness of CE is substantial, that of efficacy marginal; a minimally-invasive CE strategy also implies a filter for post-CE [polypectomy] referrals. Based on uptake for CE in other areas of the GI tract (small bowel, esophagus), there is ubiquitous expectation that CE will achieve better acceptance and thus will increase compliance to screening. If such uptake

**Figure 1. Crucial Role of Patient Compliance in the Effectiveness of CRC Screening**



The impact of compliance on the effectiveness of CE is substantial, that of efficacy marginal. Thus, cost-effectiveness of CRC screening using PillCam COLON will mainly depend on its ability to improve compliance in the general population. The very low adherence achieved by colonoscopy prompts an urgent need for minimally-invasive alternatives, such as capsule endoscopy. PillCam COLON holds great promise in improving compliance to CRC screening standards in the general population.

**Figure 2. Cost-effectiveness CE vs Colonoscopy**



mirrors that for other cancer screenings, CE will be an efficient strategy for CRC prevention, with cost-effectiveness potentially superior to colonoscopy. PillCam COLON holds great promise in improving compliance to CRC screening standards in the general population.

## References

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- Sonnenberg FA, Beck JR. Markov models in medical decision making: a practical guide. *Med Decis Making*. 1993 Oct-Dec;13(4):322-38. <http://www.ncbi.nlm.nih.gov/pubmed/8246705>.

# CRC Screening and Other Indications

Several presentations focused on studies and patient cases using PillCam COLON for CRC screening as well as other indications complementing colonoscopy, ie, patients unwilling or unable to have colonoscopy. S. Chaussade (France) presented interim data on behalf of the French Ministry of Health research grant consortium (PHRC) study led by J. Galmiche (France). In his conclusions, Chaussade emphasized the “excellent acceptability and tolerance of PillCam COLON in patients screened for colonic neoplasia.” During presentations of the patient cases (this page), there were interactive questions to the audience that stimulated lively discussions on challenging aspects of the different cases and patient management strategies involving CCE and follow-up modalities.

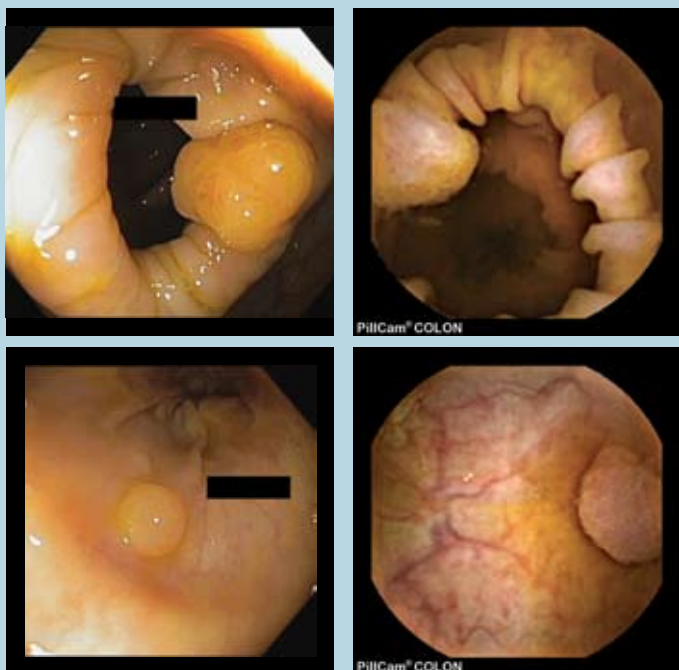
*Note: Images not marked PillCam COLON are from colonoscopy.*



### Adenomatous polyps

CRC screening of patient with family history of adenomatous polyps; she presented with occasional upper gastric pain and reflux; no weight loss or anemia/bleeding. CCE findings: Multiple polyps were identified. Post-CCE: Colonoscopy and polypectomy of 6 polyps was performed: 4 were adenomas. Patient is well and scheduled for follow-up colonoscopy in 2 years.

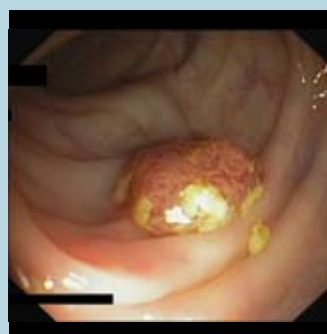
*M. Philipper, Evangelisches Krankenhaus, Duesseldorf, Germany*



### Hyperplastic polyps

Patient presented with upper- and mid-abdominal pain for 6 months and had normal bowel habits, no visible blood in stool, and no weight loss. CCE findings: 4 polyps were detected. Post-CCE: colonoscopy and polypectomy were performed: 4 hyperplastic polyps (1 polyp was > 1 cm in transversum).

*M. Keuchel, Asklepios Klinik Altona, Hamburg, Germany*



### Serrated adenoma in sigmoid colon

CRC screening of asymptomatic patient with hypertension and no personal or family history of colonic polyps or cancer. Patient refused colonoscopy and requested a minimally-invasive, comfortable method of CRC screening. CCE findings: Pedunculated polyp in sigmoid colon was detected. Post-CCE: Based on CCE findings, patient agreed to colonoscopy (to confirm CCE findings) and polypectomy. Histological diagnosis: serrated adenoma. Patient is well and scheduled for follow-up in 1 year.

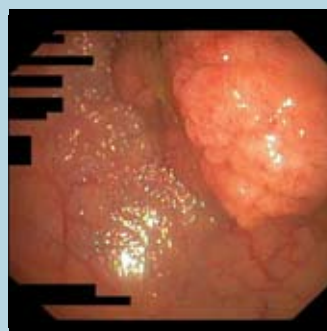
*J. M. Herreras, Hospital Universitario Virgen Macarena, Seville, Spain*



### Hyperplastic polyp

Patient presented for regular CRC screening (for adults ≥ 55 years old, according to regional guidelines) with no major complaints except infrequent diarrhea. CCE findings: 1 small polyp was detected. Post-CCE: colonoscopy was performed; polyp was removed during biopsy. Histologic diagnosis: hyperplastic polyp. Patient is well with no symptoms after 1 year.

*A. Sieg, Gastroenterologische Schwerpunktpraxis, Heildelberg, Germany*



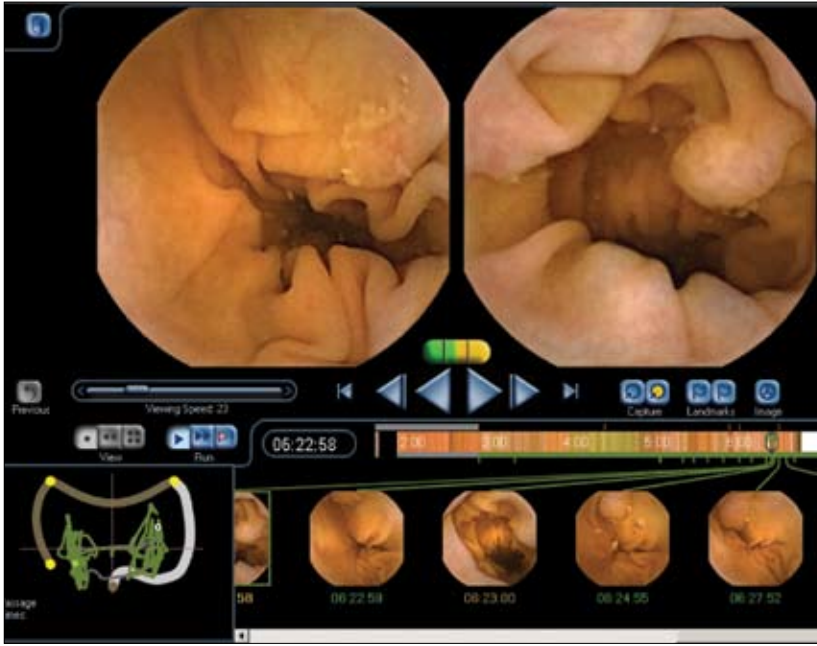
### Tubulovillous adenoma in rectosigmoid colon

Patient had complaints of constipation alternating with diarrhea and no weight loss, no anemia/rectal bleeding. She had prior history of breast cancer (surgery, chemotherapy) and chronic GERD. CCE findings: Polyp in the rectosigmoid colon was detected.

Post-CCE: Biopsies via colonoscopy were performed. Histological diagnosis: tubulovillous adenoma, moderate but focal high-grade dysplasia. Surgery: Resection (15 cm) of the rectosigmoid by laparoscopy. Follow-up colonoscopy showed absence of lesion at > 1 year post-surgery. Patient is well and next follow-up is in 3 years.

*A. Van Gossom, Erasme Hospital, Brussels, Belgium*

## Workflow and Practical Guidelines



As with any new modality, colon capsule endoscopy involves a learning process—the PillCam COLON video capsule is unique in enabling direct visualization of colon mucosa through clear fluid without using insufflation.

J. M. Herrerías (Spain) and M. E. Riccioni (Italy) gave presentations that focused on practical guidelines and how CCE can fit into the workflow of a GI practice. Riccioni described the various RAPID features for effective reading of PillCam COLON videos as well as tips for using:

- Schematic Colon Track, a tracing tool for localization allowing convenient and quick identification of the colon section being viewed (right, transverse, or left colon)
- Image Enhancement and Adjustment
- Polyp Size Estimation

At the conclusion of the workshop, Herrerías proposed detailed diagnostic algorithms for CCE for CRC prevention and other indications for colonic examination. Such algorithms can stimulate discussion and future studies about where CCE with PillCam COLON fits in the workflow with other diagnostic modalities.

In his closing remarks at the 1st International ICCE Workshop on Colon Capsule Endoscopy, co-chair G. Costamagna (Italy) concluded:

*“This is only the beginning—the best is yet to come.”*

To learn more about CCE, visit [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org) or contact your Given Imaging representative for educational opportunities such as courses, presentations at international congresses, professional societies, and local capsule clubs.

## Recipients of Awards Presented at ICCE

The European Capsule Endoscopy Group (ECEG), established during United European Gastroenterology Week (UEGW) 2004 in Prague, initiated the ECEG Research Grant “to support innovative research in gastroenterology with substantial involvement in capsule endoscopy.” At ICCE Berlin, Chairman of the ECEG Research Grant Committee T. Ponchon (France) announced the recipients of the 2008 grants:



- Principal Investigator I. Fernández-Urién (Spain) for a pilot, prospective 6-site multicenter study on the role of CE in patients with Stage III-IV melanoma.
- Principal Investigator H. Glerup (Denmark) and the research team of B. Larsen, R. Oestgaard, B. Deuleran for their study using CE to evaluate Crohn’s disease in ankylosing spondylitis.

See [www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org) for online application information for ECEG Research Grants.

**Many thanks to those who contributed to this ICCE Workshop Report.  
Visit [www.ICCE.info](http://www.ICCE.info) for important information on the conference and  
[www.CapsuleEndoscopy.org](http://www.CapsuleEndoscopy.org) for more information on capsule endoscopy.  
See you at the next ICCE.**

Ellen F. Bodner, Editor, ICCE Workshop Report

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