

***From the Digestive Disease Week Meeting,
Orlando, Florida***

Trial Finds Capsule Endoscopy Safe and Effective For Pediatric Use

Results of the first study in pediatrics presented at Digestive Disease Week 2003 shows capsule endoscopy to be more accurate and patient friendly than traditional imaging modalities

Clinicians from Sainte Justine Hospital in Montreal announced that their recently completed study demonstrated that the M2A[®] capsule endoscope can safely and accurately diagnose small bowel disorders in children. The results of the study demonstrate that capsule endoscopy offers a more accurate and non-invasive approach for diagnosing small bowel disorders in children over the age of ten when compared to traditional imaging modalities. Ernest G. Seidman, M.D., Chief, Division of Gastroenterology, at Sainte-Justine Hospital in Montreal, and his team conducted this comparative, self-controlled study involving 30 pediatric patients between the ages of 10 and 18.

“Based on the results of the study, capsule endoscopy is a safe and more effective diagnostic tool for pediatric patients older than 10 who suffer from obscure small bowel disorders not diagnosed by other imaging modalities” said Dr. Seidman. “In light of the growing body of positive clinical data from use of the capsule endoscope in adults, we are pleased that children and adolescents can also benefit from the technology’s superior diagnostic and validation capabilities.”

The study aimed to evaluate the sensitivity, specificity and global diagnostic value of the M2A diagnostic system in identifying specific occult small bowel disorders in children and adolescents. Thirty pediatric patients suspected of having small bowel disorders, including occult Crohn’s disease, intestinal polyposis and obscure GI bleeding were examined. The trial compared the results of the videocapsule procedure for each case with the corresponding traditional imaging for the above three disorders. The capsule endoscope was well tolerated by all patients and no adverse effects were reported.

Of the thirty patients studied, the capsule endoscope correctly diagnosed or definitely excluded a bleeding source, small bowel polyps or Crohn’s Disease in twenty-nine cases. In the one remaining case, the patient spontaneously stopped bleeding during the course of the trial and no diagnosis was made using any type of imaging procedure. This is the first clinical trial of the M2A capsule in children. The U.S. Food and Drug Administration (FDA) has not yet reviewed the M2A capsule for pediatric use.

Study Shows Zelnorm Effective and Well Tolerated For Treating Chronic Constipation

Novartis Plans to Submit Trial Results to Regulatory Agencies for Potential New Indication

Zelnorm[®] (tegaserod maleate) was found significantly more effective than placebo in providing rapid and sustained relief from chronic constipation during 12 weeks of therapy based on a pivotal trial with 1,348 female and male patients. Zelnorm also provided relief of several chronic constipation symptoms including abdominal discomfort or pain, bloating or distension, straining and stool consistency.

The new data, included findings that further support the safety and tolerability profile of Zelnorm. A submission to the U.S. Food and Drug Administration (FDA) for the drug’s use in patients with chronic constipation is planned for the fourth quarter of 2003. Zelnorm is approved currently by the FDA for the short-term treatment of women with Irritable Bowel Syndrome (IBS) whose primary bowel symptom is constipation.

“If approved for use in chronic constipation, Zelnorm would be the first treatment not only to improve bowel frequency but also to provide relief of multiple symptoms to patients,” said John Johanson, MD, MSC, lead investigator and clinical associate professor of medicine at the University of Illinois College of Medicine in Rockford. “This advance would be welcomed by the medical community because there is a need for additional therapies that are effective and well tolerated.”

This study defined chronic constipation as symptoms for at least six months duration with less than

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three complete spontaneous bowel movements (CSBM) per week and straining, incomplete evacuation and/or hard stools. Ninety percent of the patients in the study were women who had constipation symptoms for an average of 19 years.

EIF's National Colorectal Cancer Research Alliance Introduces First-Of-Its-Kind Educational CD-ROM Narrated by NCCRA Cofounder Katie Couric

The Entertainment Industry Foundation's National Colorectal Cancer Research Alliance (NCCRA) unveiled a new educational CD-ROM—narrated by co-founder Katie Couric—to help people better understand colorectal cancer prevention, tests and treatments.

The multimedia CD-ROM was created with help from leading physician groups, including the American Gastroenterological Association, American College of Obstetricians and Gynecologists, American Society of Colon and Rectal Surgeons, and the Foundation For Digestive Health and Nutrition, as well as NCCRA's prestigious Medical Advisory Board. The project marks the first time these professional groups have collaborated in this way.

“Colorectal cancer is the second-leading cause of cancer deaths in the United States and still kills more Americans than any other cancer except lung cancer,” says Couric, co-anchor of NBC's TODAY. “With this CD-ROM, we want to help take the fear out of getting screened for the disease. Colon cancer can be cured more than 90% of cases when it's caught early.”

The goal is to give people convenient and easy-to-understand information about this highly preventable disease. The CD-ROM also arms physicians themselves with material on the latest advances in screening and treatment guidelines. Focused on prevention, this comprehensive disk features:

- Ground-breaking video simulation of the growth of a polyp, the precursor to all cases of colon cancer. The footage is derived from actual patient scans performed by medical experts at the USC/Norris Comprehensive Cancer Hospital in Los Angeles. USC/Norris provided funding and scientific guidance to Anatomical Travelogue Inc., an award-win-

ning company that, in turn, produced the 3D images.

- NBC TODAY's award-winning series on colon cancer including Couric's on-air colonoscopies.
- In-depth information about screening tests, treatments, and other resources endorsed by leading professional gastroenterology organizations.
- A special section specifically for physicians that provides the latest scientific reports, medical articles and web links for more information.
- NCCRA's library of public service messages including testimonials from celebrities who have been touched by colon cancer in some way.
- An introduction to the Jay Monahan Center for Gastrointestinal Health at New York-Presbyterian Hospital Weill Cornell Medical Center and Weill Medical College of Cornell University in New York City. This center will be a comprehensive, fully integrated and multidisciplinary program that stresses education and prevention in addition to the diagnosis and treatment of GI cancers.

Development of the NCCRA's CD-ROM was underwritten by a grant from Pharmacia Oncology. 21-CD provided technical production and Sagon-Phior created the interface design. Initially, 200,000 CD-ROMs have been produced and will be distributed to select physicians as part of the pilot phase of this project.

About National Colorectal Cancer Research Alliance

The NCCRA is dedicated to the eradication of colon cancer by promoting education, fundraising, research and early medical screening for the disease. The NCCRA was co-founded in March of 2000 by NBC TODAY show co-anchor Katie Couric, nationally known cancer fund raiser Lilly Tartikoff, and the Entertainment Industry Foundation.

About Entertainment Industry Foundation

The NCCRA is a program of the Entertainment Industry Foundation. As the philanthropic heart of the entertainment industry, EIF has distributed hundreds of millions of dollars—and provided countless volunteer

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BRIEF MEETING REPORTS

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hours—to support charitable initiatives addressing some of the most critical issues facing society today.

Pfizer's CELEBREX® (Celecoxib Capsules) Linked To Significantly Lower Incidence Of Medication-Induced Damage To The Small Bowel

Data Also Show High Incidence of Ulcer-like Lesions in Apparently Healthy People Undergoing Screening Prior to Study Treatment

Data from so-called “capsule endoscopies” using videocamera-in-a-capsule technology showed that Celebrex (200 mg taken twice daily) was linked to a nine-fold lower incidence of mucosal lesions developed in the small bowel, compared to treatment with a combination of naproxen (500 mg taken twice daily) omeprazole (20 mg daily).

“These data extend our understanding of the gastrointestinal safety of celecoxib beyond what is already

known. They add further evidence that chronic blood loss and development of anemia associated with non-specific nonsteroidal anti-inflammatory drugs may be related to medication-induced damage along the entire length of the small bowel tract, where proton pump inhibitors (PPIs) like omeprazole do not confer protection,” said Dr. Jay Goldstein, Professor of Medicine and Vice Head for Clinical Affairs, Department of Medicine, Section of Digestive and Liver Diseases, University of Illinois, Chicago, Illinois. “They also expand the celecoxib GI safety profile by broadening the concept of GI safety beyond safety in the upper GI tract alone,” Dr Goldstein said.

The study also showed a surprisingly high percentage (13.8%) of apparently healthy people with no history of GI symptoms or disease failed initial screening due to the presence of small bowel abnormalities detected by this new capsule technology. “These findings provide us with important new information on the background rate of mucosal abnormalities in the small bowel,” said Dr. Goldstein, the study’s lead investigator.

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Please include your name, address, affiliations, and telephone and fax numbers.

GASTROENTEROLOGY OPPORTUNITY

The Medical Service, Gastroenterology Section, of the VA Boston Healthcare System is seeking Board-Certified/Board-Eligible full-time Gastroenterologist. The individual selected will have clinical, administrative and teaching responsibilities. Responsibilities include outpatient and inpatient endoscopy, general gastroenterology clinic, house staff and fellow training, and inpatient consultation. Interest in colorectal cancer screening favored. Ability and experience to perform interventional procedures welcomed. We offer opportunities for clinical research in addition to teaching medical students and fellows.

Qualified candidates should forward CV to: Anthony Catanese, AO Medical Svc., 1400 VFW Parkway, West Roxbury, MA 02132.

Heart Failure Complicating Infliximab Therapy

Forty-seven patients who developed new or worsening heart failure during TNF antagonist therapy were reported as case studies. Thirty-eight patients developed new onset heart failure and nine patients experienced heart failure exacerbation after TNF antagonist therapy (Infliximab or Etanercept) for rheumatoid and other arthritis and Crohn's disease. Of the 38 patients with new-onset heart failure, 19 (50 percent), had no identifiable risk factors. Ten patients younger than 50 years of age developed new-onset heart failure after receiving these antagonists. After TNF antagonist therapy was discontinued and heart failure therapy was started in these ten patients, three had complete resolution of heart failure, six improved and one died.

It was concluded that in a fraction of patients, TNF antagonists might induce new-onset heart failure or exacerbate existing disease. (Kwon HJ, Cote PR, Cuffe MS, et al. "Case Reports of Heart Failure After Therapy With a Tumor Necrosis Factor Antagonist." *Annals of Internal Medicine*, 2003; Vol. 138, pp. 807-811.)

Constipation in Colon Cancer

A population-based, case-controlled study was reported, defining constipation as fewer than 3 reported bowel movements per week, including subjects between ages 40 and 80 years old residing in urban and rural communities of North Carolina, questioning bowel habits and laxatives during face-to-face interviews with 643 cases (349 white, 294 black) and 1,048 controls.

There was a greater than two-fold risk of colon cancer among those with constipation, adjusted for age, race, sex and relevant confounders. The association was greater for women than for men and stronger in blacks than in whites. Black women have the highest risk, which remained significant, even after excluding subjects with late stage distant disease. There was no correlation with laxative abuse, although fiber commercial laxatives appeared to exert a protective effect in a small subgroup.

The study provided support for positive association with constipation and increased risk for colon cancer, with women (especially black women), with constipa-

tion seeming to be at the highest risk. (Dempsey R, Millikan RC, Galanko JA, et al. "Constipation, Laxative Use and Colon Cancer in a North Carolina Population." *American Journal of Gastroenterology*, 2003; Vol. 98, pp. 857-864.)

Stent Therapy in Chronic Pancreatic Pain

Twenty-five consecutive patients had 40 stent placement episodes. The main pancreatic duct diameter, grade of pancreatitis and preexisting obstructive lesion and stent-induced strictures were recorded. Pain response and stent patency were correlated with the main pancreatic duct caliber change. In 28 of 40 episodes (70 percent), the main pancreatic duct caliber increased or was unchanged after stenting. Pain improved in 20 of 28 (71 percent). Pain improved in six (50 percent) of 12 patients with smaller ducts after stenting. Stent patency was documented upon retrieval in 34 episodes and most stents were occluded. Stent-induced strictures developed in 18 percent of 40 stent episodes.

It was concluded that main pancreatic duct caliber after endoscopic stenting was not a good indicator of pain response or stent patency. The main pancreatic duct was often larger, and even with stent inclusion, patient's symptoms were frequently improved. Stent-induced strictures were infrequent, compared with values previously reported in the literature. (Morgan D, Smith JK, Hawkins K, Wilcox CM. "Endoscopic Stent Therapy in Advanced Chronic Pancreatitis: Relationship Between Ductal Changes, Clinical Responses and Stent Patency." *American Journal of Gastroenterology*, 2003; Vol. 98, pp. 821-826.)

Ineffective Motility and GERD

Seventy-two patients with esophageal-presenting symptoms, 12 of which had supraesophageal symptoms, were evaluated retrospectively, utilizing a database review of 84 patients in a GI physiology laboratory. The prevalence of abnormal esophageal acid exposure was similar in patients with esophageal and supraesophageal symptoms. Abnormal motility was identified in 26 patients (31 percent). Ineffective

motility was the most common motility disorder, and was present in 77 percent, or 20 patients. The frequency of motility disorders was similar in patients with and without abnormal esophageal acid exposure, and in patients with esophageal or supraesophageal symptoms, and similar with upright, supine and combined reflux.

It was concluded that ineffective esophageal motility does not stand alone as a significant marker for the presence of gastroesophageal reflux disease in general, or supraesophageal reflux disease in particular. (Vijayarayer E, Gonzalez B, Brensinger C, et al. "Ineffective Motility Is Not A Marker For Gastroesophageal Reflux Disease." *American Journal of Gastroenterology*, 2003; Vol. 98, pp. 771-776.)

Transmission of Hepatitis C Virus in HIV Coinfections

A prospective enrollment of 347 subjects, including 87 family members of 53 HCV/HIV coinfecting index cases and 134 family members of 73 HCV mono-infected index cases served as a control group. All were interviewed and appropriate laboratory studies were carried out. A meta-analysis designed to assess the pooled risk of sexual transmission of HCV among HCV/HIV coinfecting patients was performed.

Anti-HCV was detected in 2.2 percent of family members of HCV mono-infected index cases and 2.3 percent of family members of HCV/HIV coinfecting index cases. The viral load was higher in coinfecting index cases, compared with HCV alone. HCV concordance was observed in 3 family members of HCV mono-infected cases and in 2 family members of HCV/HIV coinfecting index cases.

It was concluded that the data demonstrated a low prevalence of intrafamilial transmission of HCV, independent of the presence of HCV/HIV coinfection. This finding was supported by meta-analysis, failing to identify HIV as an important cofactor of sexual transmission in HCV/HIV coinfecting patients. (Keyserman DR, Both CT, Mattos AA, et al. "Intrafamilial Transmission of Hepatitis C Virus in Patients with Hepatitis C Virus in Patients With Hepatitis C and Human Immunodeficiency Virus Coinfection." *American Journal of Gastroenterology*, 2003; Vol. 98, pp. 878-883.)

Murray H. Cohen, D.O., editor of "From the Literature" is a member of the Editorial Board of *Practical Gastroenterology*.

There isn't a physician who hasn't at least one "Case to Remember" in his career.

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Colonic Diseases

Timothy R. Koch, Editor

Humana Press, New Jersey, 2003

553 pages; ISBN: 0-89603-961-7; \$175.00

The title of this book is a misnomer. While the reader expects an in depth review and discussion of the recent literature on colonic diseases, it focuses on the physiology and morphology of the normal colon. Only one fourth of the 553 pages are devoted to diseases of the colon. As a result, this textbook has its greatest value for those interested in the basics of colonic morphology and function and perhaps for physicians with a special interest in investigational tools. Chapters on anorectal and colonic motility studies are probably among the best I have ever read on these subjects.

However, if it comes to the discussion of colonic diseases, the reader should be prepared for a harsh disappointment. For example, while twenty pages of this textbook are devoted to a rather uncritical discussion of the use of probiotics in colonic diseases, less than half of this space is assigned to ulcerative colitis. Consequently, important complications of the latter disease are either barely mentioned (sclerosing cholangitis) or not at all (toxic megacolon). Unfortunately, this is not the only omission. If one searches for infectious diseases of the colon, appendicitis, solitary rectal ulcer, proctalgia fugax, pelvic floor dyssynergia, etc. one will find no more than a sentence here and there or no mention at all. In addition, one often is left with the impression that the authors give their very personal view of how one should diagnose and treat certain diseases rather than providing an objective account of the current literature. This impression becomes most evident in the chapters on constipation and anorectal disorders where one, for example, is astonished to read that treatment with nitroglycerine or botulinum toxin "are not yet proven or standard of care".

The making of this book also leaves much room for improvement. Reference and figure numbers in the text occasionally do not match with the list of references and figures reproduced in this book. Endoscopic images that are reproduced in black and white are sometimes hardly recognizable as such and color photographs are lumped in the center of this book without providing any legends.

In summary, if the potential reader is mainly interested in colonic physiology and methods of its investiga-

tion, this book is probably a good buy. However, if one wants to get in-depth information on what the title suggests, one is much better served by the widely available general textbooks of gastrointestinal disorders.

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FALK WORKSHOP: Bile Acids and Pregnancy

Leuschner J, Berg PA, Holtmeier J, Editors

Kluwer Academic Publishers, 2002

ISBN: 0792387821; \$56.00

This short book contains a series of presentations from the June 2002 Falk Symposium on bile acids and pregnancy. It covers three main topics: the effect of pregnancy on the maternal immune system; the interrelation of bile acids and pregnancy in intrahepatic cholestasis of pregnancy (ICP) and in other cholestatic liver diseases; and the impact of ursodeoxycholic acid (UDCA) on bile acid metabolism and these conditions. There are 12 different chapters or presentations and each presents an excellent up-to-date summary of the relevant data on a specific topic followed by a comprehensive list of references.

The book contains the format characteristic of the Falk conferences. There are chapters on basic science, followed by presentations on clinical research data and discussions on applications of both for clinical practice. The combination of presentations emphasizes how integrating basic science and clinical data allows one to achieve a better understanding of a complex disease. The chapters on basic immunology and bile acid metabolism in pregnancy are well written for the clinician and provide a relevant insight into this complex topic. The chapter on the effects of UDCA on the mother and the fetus provides a summary of available data supporting treatment of ICP with UDCA.

This book provides an excellent resource for those immunologists, gastroenterologists, hepatologists and gynecologists who are interested in, and treat, women with ICP and cholestatic liver disease. I found myself reading this interesting book cover to cover and wishing I had attended the conference. I would recommend this book as a worthwhile read on its own and would encourage clinicians who are confronted with

cholestatic liver disease in pregnancy to refer to it for its content and references.

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Clinical Geriatrics

Dharmarajan TS and Norman RA, eds
Parthenon Publishing, 2003, New York, NY
ISBN: 1842141120; \$89.95

Clinical Geriatrics is a relatively short review (about 650 pages) of medical problems faced by the geriatrician. It is divided into 5 sections, Principles of Geriatrics, Geriatric Syndromes, Geriatric Neuropsychiatry, Systems/Organ Involvement, and Miscellaneous. There are many references from 2002.

The GI section is too brief and condensed to be of any use to gastroenterologists either in practice or in training. There is an 11-page chapter on Constipation and Fecal Incontinence and a brief chapter (13 pages) on The Gastrointestinal System. On the other hand there is a 7 page chapter on Polymyalgia Rheumatica and Temporal Arteritis.

For a non-geriatrician this book has many pearls and suggestions but I suspect they are not particularly new or pearls to someone in the field. This might be a good book for a Family Practice Resident or Internal Medicine resident to review during their training.

George Meyer, MD
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Looking Back (and Forth):

Herbert L. Fred, M.D.
Mercer University Press, 2003
ISBN: 0-86554-722-6; \$30 (\$24 on-line)

In his forty-four years as a master clinician and medical educator, Dr. Fred has seen a radical shift from medical care that is humane and patient-centered to one that is driven by technology, laboratory tests, and the insurance industry. During these forty-four years he has managed to record his observations, frustrations, admonishments and advice in a series of articles which is reproduced in one concise volume. His style is light (despite the seriousness of the subject matter), readable, and compact. He illustrates his points with specific case presentations and recollections of actual events and encounters. He covers many topics from “I Remember When” to “Requiem for

the Ophthalmoscope” or “Five Cases in Search of a Diagnostician” to “C.T. Scanner Dies.”

Dr. Fred has dedicated his life to teaching medical students and residents in internal medicine the ideal basic principles of being a good physician. These principles include honesty, the constant seeking of excellence, avoiding arrogance, promoting skepticism, and always putting patients first. He emphasizes the importance of a carefully obtained history, a thorough physical examination, and the critical and thoughtful synthesis of the findings into a plan that is constantly re-evaluated and re-examined. The patient remains the center of all thoughts and activities—not the physician or the nursing staff.

Algorithms by their mechanical and thoughtless nature are not in great favor with Dr. Fred. Nor is the common practice of chasing and treating laboratory numbers. He abhors the mechanical, technical, and procedural approach to patients which has so often replaced the careful and thoughtful approach of yesteryears.

No one segment of the medical profession or of the educational enterprise is allowed to escape Dr. Fred’s critical, but constructive, attention. He bemoans the health-care delivery system which is “forcing physicians to churn through patients in assembly-line fashion at an ever-accelerating rate.”

Dr. Fred is the teacher and physician all of us wish for ourselves and our family members. He is not against technology but against its thoughtless overuse and over-reliance. He encourages all of us to use our senses, our knowledge and critical thinking and to practice medicine in a humane, patient-centered way. He is very cognizant of the enormous progress that has been made in the detection and treatment of diseases. However, he would like to see all of us restore some of the “high touch” medicine where the patient is still the center of attention and where “high tech” laboratory numbers are used thoughtfully and with care.

I recommend this book as a stimulating treatise for the neophyte as well as the senior physician. The musing of this master clinician and teacher can reawaken and reinforce the basic reasons that motivated most of us to chose medicine as our calling.

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George W. Meyer, M.D., Book Editor, is on the Editorial Board of *Practical Gastroenterology*