Positive Options for Colorectal Cancer, Self-Help and Treatment
Carol Ann Larson
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Positive Options was written by a survivor of colon cancer for those who have been recently diagnosed with colon cancer, for family and friends of colon cancer patients, and for those who just want to be informed maybe because of a family history of colon cancer.

The American Cancer Society estimates there will be 145,290 new cases of colon cancer in the United States in 2005; of those approximately 56,290 will die. Colon cancer is a very real and serious threat and as the book states “what’s regrettable is that despite these alarming figures, there is an underuse of screening among Americans.” Books like these can help decrease social taboos and fears, people need to pay attention to their bodies and be able to talk about their bowel habits when they notice something has changed.

Carol Ann Larson has written this text from the perspective of a survivor of colon cancer. She faced the fear of a diagnosis of cancer, she experienced the embarrassment of discussing a taboo subject, and she realized the power of knowledge to fight this disease. Carol put together a book loaded with practical tips from others who have also experienced these problems personally.

In just 10 short, easy to read, and straightforward chapters, Carol has addressed questions that immediately come to mind when a diagnosis of cancer is first pronounced. She also addresses issues like ‘dealing with your feelings,’ ‘what you should take to the hospital,’ ‘challenges to chemotherapy,’ and more importantly ‘life after colon cancer.’ Along the way, there are short stories and offerings from other people who survived colon cancer because who better to help you along a journey than someone who has gone before.

This book is a wealth of information for anyone who has a colon and is aging. I found it very informative, packed with up to date information and facts. A good read for anyone who is facing colon cancer.

Rhonda Gage
Sacramento, CA

George W. Meyer, M.D., Book Editor, is on the Editorial Board of Practical Gastroenterology.
Endoscopic Balloon Dilation Compared with Sphincterotomy For Extraction of Bile Duct Stones

A randomized, controlled, multicenter study of 117 patients assigned to dilation and 120 to sphincterotomy was performed in a spectrum of clinical and academic practices. Procedures were successful in 97.4 percent and 92.5 percent of the patients, respectively. Overall, morbidity occurred in 17.9 percent and 3.3 percent, respectively and severe morbidity, including two deaths, in 6.8 percent and 0 percent, respectively for dilation and sphincterotomy.

Complications respectively included pancreatitis (15.4 percent and 0.8 percent); cystic duct fistula (1.7 percent and 0 percent); cholangitis (0.9 percent and 0.8 percent); perforation (0 percent and 0.8 percent); cholecystitis (0 percent and 0.8 percent). There were two deaths, due to pancreatitis following dilatation and none with sphincterotomy. The study was terminated at the first interim analysis. Dilation patients required significantly more invasive procedures, longer hospital stays, and longer time off from normal activities.

It was concluded in a broad spectrum of patients and practices, that endoscopic balloon dilation, compared with sphincterotomy for bile duct extraction, is associated with increased short-term morbidity rates and deaths, due to pancreatitis. Balloon dilation in the sphincter of Oddi for stone extraction should be avoided in routine practice. (Disario JA, Freeman ML, Bjorkman BJ, et al. “Endoscopic Balloon Dilation Compared with Sphincterotomy for Extraction of Bile Duct Stones.” Gastroenterology, 2004; Vol. 127, 1291-1299.)

Etodolac Vs. Naproxen and Clinically Significant Upper Gastrointestinal Events

An historical cohort study was performed in which 16,286 veteran patients received Etodolac or Naproxen during a 3-year period without concurrent use of other ulcerogenic drugs, other than low dose aspirin. The primary outcome was the CSUGI (clinically significant upper gastrointestinal events) rate of the two groups without concomitant low dose aspirin.

The incidence of CSUGI events was 0.78 percent and 0.24 percent for Naproxen and Etodolac, respectively. In the NSAID-naive subset, the incidence of these events was 0.99 and 0.24 for the two drugs, respectively. Compared with Naproxen, Etodolac was associated with a reduction in upper gastrointestinal events.

Concomitantly used low dose aspirin increased event rates with Naproxen twofold and Etodolac ninefold. There was no significant difference in gastrointestinal event rates between the two when low dose aspirin was taken concomitantly.

It was concluded that Etodolac is a generic COX-2 selective inhibitor that reduces CSUGI events, compared with a nonselective NSAID, Naproxen. However, concomitant use of low dose aspirin negates the gastrointestinal safety advantages of the Etodolac. (Ed. note: It is unknown whether or not Etodolac is associated with increased cardiovascular thrombotic events. The current study did not evaluate these events and future studies will be required to assess its cardiovascular safety.)(Weidman RA, Kelly KC, Kazi S, et al. “Risks of Clinically Significant Upper Gastrointestinal Events With Etodolac and Naproxen: An Historical Cohort Analysis.” Gastroenterology, 2004; Vol. 127, 1322-1328.)

Endoscopic Treatment in Primary Sclerosing Cholangitis

In order to determine the prevalence of a dominant stricture in patients with PSC and spontaneous course of alkaline phosphatase and bilirubin up to a year from diagnosis in patients with and without a dominant stricture, cholangiographies from 125 patients with PSC were reevaluated. Dominant stricture was defined as a stenosis equal to or greater than 1.5mm in diameter of the common bile duct, and/or equal or less than 1mm of the right hepatic duct or left hepatic duct.

A dominant stricture was present in 56 of 125 patients (45 percent). The patients’ mean values for alkaline phosphatase were identified. The changes in alkaline phosphatase and bilirubin observed from the precholangiographic value up to 2 and 12 months afterward were not significantly different in those with and without dominant strictures. It was concluded that cholestasis in patients with PSC does not seem to be related to the presence of dominant strictures. Endo-
scopic therapy of dominant strictures should not be routinely undertaken. Randomized studies are needed to clarify therapy in reference to potential benefits. (Bjornsson E, Lindqvist-Ottison J, Asztkly M, Olsson R. “Dominant Strictures in Patients with Primary Sclerosing Cholangitis.” Amer J Gastroenterol, 2004; Vol. 99:542-506.)

**Colon Ischemia in IBS**

Using medical claims data from a large health care organization in the United States, 87,449 people were identified with an IBS diagnosis between January, 1995 and December, 1999. Calculation of the age and sex-specific incidence rates of colon ischemia were identified in the general population and in irritable bowel syndrome patients.

There were 740 cases of colon ischemia during 8.5 million person/years of observation in 5.4 million persons. The accrued incidence rate was 42.8 cases per 100,000 person/years for IBS patients. By comparison, the incidence rate was 7.2 per 100,000 person/years in the general population.

After adjustment for age, sex and calendar year, the incidence of colon ischemia in people with IBS was 3.4 times higher than a person without that syndrome.

It was concluded that the rate of colon ischemia among patients carrying a diagnosis of irritable bowel syndrome are substantially higher than in the general population. Colon ischemia, though unusual in irritable bowel syndrome patients, may nonetheless constitute a distinct part of the IBS natural history. Alternatively, it may be a consequence of therapy or a manifestation of other bowel pathology that is sometimes confused with IBS. (Cole JA, Cook SF, Sands BE, et al. “Occurrence of Colon Ischemia in Relation to Irritable Bowel Syndrome.” Amer J Gastroenterol, 2004; Vol. 99:486-491.)

**6-MP in Ulcerative Colitis—Optimal Duration of Treatment**

Records from the Inflammatory Bowel Disease Center at Lenox Hill Hospital and one large IBD practice in New York City of 334 patients treated with 6-MP for ulcerative colitis were reviewed. They were followed from 4 months to 28 years. Sixty-one patients were treated with 6-MP for at least six months and had at least a 3 month disease-free interval off steroids while on the medication. The patients were divided into two groups. Group #1 continued 6-MP and Group #2 discontinued the drug at various times for reasons other than relapse. Time to relapse was calculated for both groups.

A Kaplan-Meier survival analysis was employed. The median time to relapse in Group #2 was 24 weeks and in Group #1 58 weeks. There were no significant differences between the two groups in age, gender, extent of disease, use of concomitant 5-ASA products, dose of 6-MP during remission, duration of ulcerative colitis and duration of treatment with 6-MP before remission was achieved.

It was concluded that discontinuance of treatment with 6-MP while ulcerative colitis is in remission leads to a higher relapse rate than maintenance on 6-MP and
indefinite treatment with 6-MP was favored in most patients. (Lobel BZ, Korelitz BI, Xuereb MA, Panagopoulos G. “A Search For The Optimal Duration of Treatment with 6Mercaptopurine For Ulcerative Colitis.” Amer J Gastroenterol, 2004; Vol. 99: 462-466.)

Bernstein Testing Vs. Prolonged pH Monitoring

Ninety-three patients with heartburn underwent 24 hour pH monitoring and Bernstein testing. A Bernstein score that included the severity of the heartburn and the time of heartburn onset during the test was calculated. The relationship between symptom index determined from prolonged pH recording, Bernstein test and Bernstein score was determined.

Fifty-eight patients reported symptoms during the prolonged pH recording. A positive symptom index was determined in 27 patients. Forty-nine patients had a positive Bernstein test. There was no correlation between the patients with the two separate positive test results or between the symptom index and Bernstein score. A positive Bernstein test within 5 minutes of acid infusion did not predict heartburn during spontaneous reflux episodes of greater or equal to 5 minutes.

The lack of association between symptoms induced by acid perfusion of the esophagus, compared with symptoms following spontaneous reflux in the same individual suggests that the heartburn following acid perfusion and spontaneous heartburn are induced by different stimuli. The data supported the concept that two distinct triggers may lead to heartburn, one that induces spontaneous heartburn and another that induces heartburn during acid infusion into the esophagus. It was speculated that spontaneous heartburn may be the result of motor events in the esophagus. Chronic heartburn may be multifactorial in origin. (Yung B, Steinbach J, Beaumont C, Mittal RK. “Lack of Association Between Esophageal Acid Sensitivity Detected by Prolonged pH Monitoring and Bernstein Testing.” Amer J Gastroenterol, 2004; Vol. 99: 410-415.)

Infliximab in Fistulizing Crohn’s Disease

Sixty consecutive patients with fistulous Crohn’s disease and at least 3 months of follow-up after 3 Infliximab infusions were evaluated. Patients with enteroenteric fistulae were excluded. Complete response was defined as complete closure of the fistulae or complete cessation of fistula drainage.

Thirty-five patients had external fistulae, 16 had internal fistulae, and 9 had mixed (both external and internal fistulae). Complete response rates were significantly higher in patients with external fistulae (69 percent), compared with those with internal fistulae (13 percent), or those with mixed fistulae (11 percent).

In the external fistula group, patients with perianal fistulae had a higher rate of complete response (78 percent), compared to those with abdominal wall fistulae (38 percent). The rate of complete response to Infliximab was significantly lower among 14 patients with rectovaginal fistulae (14 percent), compared to those with perianal fistulae (78 percent). In the mixed fistula group, only 11 percent of the patients achieved complete response. The Cox Proportional Hazards Model showed that the hazard of relapse for smokers was
nearly twice that of nonsmokers. However, this difference did not reach statistical significance.

It was concluded that there was an association between the type of fistulae and complete response to Infliximab in patients with fistulous Crohn’s disease. External fistulae in general and perianal fistulae, in particular, have a higher rate of closure in response to Infliximab, compared to other type of fistulae. (Copard MA, Lashner HA, Achkar JP, Connor JT, Brzezinski A. “Type of Fistula Determines Response to Infliximab in Patients With Fistulous Crohn’s Disease.” Amer J Gastroenterol, 2004; Vol. 99: 445-449.)

**Preoperative Staging and Tumor Resectability In Pancreatic Cancer**

To evaluate prospectively the efficacy of different strategies based on EUS, CT, MRI and angiography in the staging and tumor resectability assessment of pancreatic cancer, all consecutive patients with pancreatic carcinoma judged fit for laparotomy were studied. Results of each of the imaging techniques regarding primary tumor, locoregional extension, lymph node involvement, vascular invasion, distant metastasis, tumor TNM stage, and tumor resectability were compared with the surgical findings. Univariate, logistic regression, decision and cost minimization analyses were performed.

Sixty-two patients with pancreatic cancer were included. Helical CT had the highest accuracy in assessing the extent of primary tumor (73 percent), locoregional extension (74 percent), vascular invasion (83 percent), distant metastases (88 percent), tumor TNM stage (46 percent), and tumor resectability (83 percent). EUS had the highest accuracy in assessing tumor size and lymph node involvement (65 percent). The decision analysis demonstrated that the best strategy to assess tumor resectability was based on CT or EUS as initial test, followed by the alternative technique in those potentially resectable cases. The decision analysis favored the sequential strategy in which EUS was used as a confirmatory technique in those patients in whom helical CT suggested resectability of the tumor. (Soriano A, Castell SA, Ayuso C, et al. “Preoperative Staging and Tumor Resectability Assessment of Pancreatic Cancer: Prospective Study Comparing Endoscopic Ultrasonography, Helical-Computed Tomography, Magnetic Resonance Imaging, and Angiography.” Amer J Gastroenterol, 2004; Vol. 99: 492-501.)

**Eosinophilic Esophagitis**

Twenty-nine patients with documented eosinophilic esophagitis diagnosed by the presence of 15 or greater eosinophils per high power field in biopsy specimens, and a significant history of chronic dysphagia for solid food (24 of 29), were evaluated clinically and endoscopically. Fourteen (48%) had a history of asthma, environmental allergy or atopy. Twenty-seven patients (93%) had abnormal endoscopic findings, including unique esophageal structural changes associated with a preserved mucosal surface that were highly atypical for acid reflux injury. These changes may occur in combination or as a primary characteristic such as uniform small-caliber esophagus, single or multiple corrugations or rings, proximal esophageal stenosis or one to two whitish vesicles scattered over the mucosal surface.

Barium contrast radiography combined with barium-coated marshmallow identified ten of the primary features identified endoscopically in 15 patients, but failed to detect other features noted at endoscopy. Eight of the 29 patients had a history of chronic heartburn. Twelve had been treated with proton pump inhibitor therapy and only 3 reported some improvement in the severity of dysphagia.

It was concluded that relatively young age, a history of chronic dysphagia for solid foods and endoscopic detection of unique structural alterations atypical for GERD in an adult patient should prompt the suspicion of eosinophilic esophagitis and subsequent biopsy confirmation. Acid reflux appeared to have a secondary role in this disorder. The incidence of eosinophilic esophagitis in adults appears to be increasing. (Potter JW, Saeian K, Staff D, et al. “Eosinophilic Esophagitis in Adults: An Emerging Problem With Unique Esophageal Features,” Gastrointestinal Endoscopy, 2004; Vol. 59: 355-361.)

Murray H. Cohen, D.O., editor of “From the Literature” is a member of the Editorial Board of Practical Gastroenterology.
Helicobacter pylori Infection and Pediatric Nonulcer Dyspepsia—No Specific Symptoms to Diagnose Infection

Infection by *H. pylori* can cause gastritis and peptic ulcer disease in children; however, it is unclear if symptoms of functional epigastric pain (nonulcer dyspepsia) are associated with a concurrent *H. pylori* infection. Therefore, a prospective, double-blind study was undertaken in Lille, France in which children 6 years or older who had symptoms of epigastric distress were evaluated by both questionnaire and endoscopy. The questionnaire was designed specifically to determine if a child had epigastric pain, and evaluated a wide range of symptoms including location and intensity of pain, frequency of pain, nocturnal awakening, hematemesis, use of medication, and number of school day absences. Ethnicity and socioeconomic levels of participants also were recorded. Upper endoscopy was performed, and *H. pylori* infection was diagnosed if a patient had bacteria identified by culture or histology. A patient was considered not infected if bacteria were not identified by culture and if normal histology of the stomach was present.

The study enrolled 100 children with a median age range of 11 years and an age range of 6 to 17 years. Twenty-six of the study subjects had *H. pylori* infection while 74 of the children had no evidence of infection. Infection with *H. pylori* was more common in non-white children and in children from low socioeconomic strata. Children with *H. pylori* infection demonstrated no significant difference in symptom characteristics compared to children with nonulcer dyspepsia in regards to nausea, vomiting, weight loss, hematemesis, lack of medication being used at time of evaluation, family history of peptic ulcer disease, and school absence. On the other hand, *H. pylori*-infected children had less epigastric pain during meals than non-infected children.

The authors conclude that outside of epigastric pain during meals, no specific set of symptoms can distinguish children with *H. pylori* gastritis from children with non-ulcer dyspepsia. The data supports the idea that *H. pylori* infection does not have a direct relationship in pediatric nonulcer dyspepsia. This study was very stringent in identifying children with epigastric pain and did not evaluate children with other vague abdominal symptoms as might be found in recurrent abdominal pain of childhood. The authors suggest that a better definition of pediatric nonulcer dyspepsia is necessary to find those children with dyspeptic symptoms who may benefit from a trial of eradication therapy. (Kalach N, Mention K, Guimand L, Michaud L, Spyckelle C, Gottrand F. “Helicobacter pylori Infection is not Associated with Specific Symptoms in Nonulcer-Dyspeptic Children.” *Pediatrics*, 2005;115:17-21).

Probiotics and Necrotizing Enterocolitis in Very Low Birth Weight Infants

Necrotizing enterocolitis (NEC) is a relatively common complication of very low birth weight infants (weight less than 1500 grams) and is associated with a high mortality rate. Its etiology is multi-factorial and includes bacterial pathogenicity, altered intestine mucosal permeability, and enteral feeding. This study from Taiwan evaluated the effect of a probiotic mixture of *Lactobacillus acidophilus* and *Bifidobacterium infantis* on the incidence and severity of NEC in very low birth weight infants. Patients were enrolled over a four-year period and were placed in a prospective, masked, randomized control trial. Three hundred and sixty-seven infants were enrolled to receive either the probiotic mixture with breast milk (180 patients) or breast milk alone (187 patients). Eligible infants weighed less than 1500 grams, survived beyond the seventh day of life, and were beginning enteral feeds.

The incidence of death or NEC was significantly lower in the probiotic patient group compared to the control group (5% versus 12.8%, *P* = 0.009). The incidence of both NEC and severe NEC also was significantly lower in the probiotic-treated group. No blood cultures obtained during the study demonstrated *Lactobacillus* or *Bifidobacterium* species. These results suggest that the enteral addition of probiotics to breast milk may reduce the incidence of death, NEC, and severe stages of NEC in very low birth weight infants. The alteration of bacterial flora by probiotic formulations may be an underlying mechanism to explain the results seen in this study. (Lin HC, Su BH, Chen AC, Lin TW, Tsai CH, Yeh TF, and Oh W. “Oral Probiotics Reduce the Incidence and Severity of Necrotizing Enterocolitis in Very Low Birth Weight Infants.” *Pediatrics*, 2005;115:1-4).
**Swallowing Pill-Sized Video Camera Gives Gastroenterologists a New Tool for Diagnosing and Evaluating Esophagus Diseases**

Patients can now swallow pill-sized, disposable cameras to help gastroenterologists diagnose and evaluate diseases of the esophagus. This new diagnostic tool is a further modification of capsule endoscopy, which has been used clinically since late 2001 to examine the small intestines.

The United States Food and Drug Administration (FDA) cleared the first version of the esophageal device (PillCam™ ESO, manufactured by Given Imaging, Israel and marketed by InScope on Nov. 29 of last year.

This new esophageal capsule endoscope is a smooth plastic capsule about the size of a large vitamin pill that has tiny video cameras at each end. A patient lies on his or her back and swallows the pill with water. The pill then glides down the esophagus taking about 2,600 color pictures, which are transmitted to a recording device worn by the patient. After 20 minutes, the doctor has enough video images to make a careful evaluation and even make a diagnosis. The disposable capsule is passed naturally, usually within 24 hours.

The esophageal capsule will be utilized to screen patients with suspected esophageal diseases such as GERD and Barrett’s esophagus, a pre-cancerous condition. However, it is important to note that the capsule endoscope is not to be used for patients who have swallowing difficulties, who wear a pacemaker or who have or are suspected of having gastrointestinal obstruction, strictures or fistulas in their digestive tract.

New information presented at the meeting of the International Conference on Capsule Endoscopy (ICCE) in March indicates this technology is useful in screening and surveillance in patients with elevated pressure in the blood vessels of the esophagus due to portal hypertension which is most often associated with liver cirrhosis. Presentations at the meeting confirmed the potential utility of the capsule endoscope to detect esophagitis and Barrett’s esophagus. In addition an international multi-center pilot trial demonstrated that this tool could be used for screening of patients with cirrhosis, esophageal varices. The 32-patient trial compared diagnostic accuracy of capsule endoscopy versus traditional upper endoscopy. All cases of esophageal varices and portal hypertensive gastropathy seen on endoscopy were detected on blinded capsule endoscope readings. A large scale validation trial will begin soon.

“Utilizing capsule endoscopy to screen patients with liver disease may increase adherence to screening and decrease sedation-related complications in this patient group,” noted Glenn Eisen, MD, ASGE Governing Board member and presenter at ICCE.

It is expected that the new capsule endoscopy will be used together with traditional endoscopy in the case management of esophageal diseases. Blair Lewis, MD, Clinical Professor of Medicine, The Mount Sinai Medical Center, NY, stated that the esophageal capsule endoscope could be used as a screening device to determine if a patient was “at risk” for cancer, while traditional endoscopy could be used to gather tissue or remove polyps.

If the patient was “at risk” for cancer, further surveillance by traditional endoscopy with tissue biopsies would be done every three years. “There were about 7,000 new cases of cancer of the esophagus in the United States last year, which is small in comparison to the cases of colon, prostate and lung cancer,” stated Dr. Lewis. “However, while the incidences of the other cancers are dropping, esophagus cancer, on a per capita basis, is growing in numbers.”

According to David J. Bjorkman, MD, president of the American Society for Gastrointestinal Endoscopy and Dean of the University of Utah School of Medicine, “The incidence of esophageal cancer is increasing faster than any other malignancy in the U.S. and much of it has to do with the fact that only 5–10 percent of patients suffering from chronic GERD actually get screened for pre-cancerous conditions.”

Of the 10 million Americans who are considered at risk for cancer in the U.S., about one million (10%) will develop Barrett’s esophagus, a pre-cancer condition. And, since Barrett’s esophagus is twice as common in men as women, deaths due to cancer of the esophagus are higher among men. About 4% of all male deaths due to all types of cancer last year were attributed to cancer of the esophagus.
“While endoscopy has been the gold standard for detecting digestive tract abnormalities,” Dr. Bjorkman said, “many patients have been reluctant to go through the procedure due to the time commitment involved, and as a result, do not get checked regularly. Capsule endoscopy could present a more attractive solution to these patients, and eventually lead to increased rates of compliance.”

Dr. Lewis stated that the goal of gastroenterologists is to get more adults over 50 screened for pre-cancer conditions of the esophagus that could lead to cancer and need to be monitored. “We hope this new patient-friendly, less intimidating capsule endoscopy procedure will increase the numbers of those willing to be screened, thus reducing the risk of cancer of the esophagus.”

For more information, please visit the ASGE website at http://www.askasge.org or call 1-866-305-ASGE.

New Recommendations by the American College of Gastroenterology
Call for Changes in Colorectal Cancer Screening of African Americans

For African Americans Screening Should Begin at 45—Five Years Before Current Guidelines
Physician experts from the American College of Gastroenterology have issued new recommendations to healthcare providers to begin colorectal cancer screening in African Americans at age 45 rather than 50 years. Colonoscopy is the preferred method of screening for colorectal cancer and data support the recommendation that African Americans begin screening at a younger age because of the high incidence of colorectal cancer and a greater prevalence of proximal or right-sided polyps and cancerous lesions in this population.

The recommendations were published in the March issue of the American Journal of Gastroenterology. Overall, colorectal cancer is the second leading cause of cancer deaths in the United States. African Americans are diagnosed with colorectal cancer at a younger age than whites, and African Americans with colorectal cancer have decreased survival compared with whites. The article reviews the evidence why African Americans should have their colons screened for cancer at age 45 instead of age 50, five years earlier than the current recommendations. The article was drafted by the American College of Gastroenterology’s Committee on Minority Affairs and Cultural Diversity.

The Committee recommends colonoscopy as a “first line” screening procedure for colorectal cancer for African Americans rather than flexible sigmoidoscopy because of the high overall risk and as well as some evidence that African Americans have more right-sided cancers and polyps. The right side of the colon includes the cecum, ascending colon and proximal transverse colon and cannot be reached by flexible sigmoidoscopy.

Clinical gastroenterologists play an important role in promoting colorectal cancer awareness and the need for screening in African Americans. Evidence suggests African Americans are more responsive to screening recommendations from their personal physicians than from other sources. The College urges physicians to provide culturally sensitive patient education on colorectal cancer to African Americans.

Reducing the high morbidity and mortality associated with colorectal cancer among African Americans continues to be a major healthcare challenge in the United States. In response to this challenge, the leadership of the American College of Gastroenterology asked the Committee on Minority Affairs and Cultural Diversity to develop a position paper on colorectal cancer in African Americans. The committee has done an extensive review of the literature on colorectal cancer screening and issues related to screening in African Americans to support their recommendations. One important goal was to improve awareness among primary care physicians and gastroenterologists of the important differences in colorectal cancer between African Americans and Caucasians.


Full text of the recommendations can be found online at the American Journal of Gastroenterology at www.amjgastro.com
Calcium and Vitamin D Most Effective For Treatment and Prevention of Bone Loss in People with Crohn’s Disease

According to a study published in Clinical Gastroenterology and Hepatology, the addition of popular bone building drugs to calcium and vitamin D therapy to treat bone loss associated with Crohn’s disease is not beneficial. Moreover, the study shows that calcium and vitamin D treatment alone can improve bone mineral density (BMD) in Crohn’s patients by 3 to 4 percent per year.

“Patients with Crohn’s often suffer loss of bone mass and an increased number of bone fractures due to treatment with corticosteroids, poor nutrition, active inflammation and calcium and vitamin D deficiencies,” said Charles Bernstein, MD, author of an editorial appearing in the journal. “Calcium and vitamin D have long been used to enhance bone mass in people with Crohn’s, and findings of these studies show it to be sufficient in maintaining BMD in these patients.”

According to results of the study from researchers at the University of Alberta, adding the bone-building drug etidronate (Ditronel) to calcium and vitamin D therapy to treat bone loss in people with Crohn’s disease adds no additional benefit. This study aimed to assess the efficacy of etidronate on bone loss in patients with Crohn’s disease, an effect that has never before been studied in patients who were not menopausal or on corticosteroid therapy.

“Calcium and vitamin D therapy alone provide benefit to Crohn’s patients who suffer from osteoporosis and osteopenia,” said Richard Fedorak, MD, study author. “We encourage physicians to look for loss of bone density in high risk patients with Crohn’s disease and to start calcium and vitamin D therapy immediately if there is either osteoporosis or osteopenia.”

Prevention and treatment of low BMD associated with Crohn’s disease includes vitamin D and calcium supplementation, education and lifestyle changes such as regular exercise and smoking cessation. Further randomized clinical trials are underway to determine if newer bone-building drugs will have additional beneficial effects on building bone mass in Crohn’s patients. The results of those studies will not be available until next year. Until then, researchers suggest vitamin D and calcium supplementation as the primary treatment for bone loss in these patients.

“These results imply that physicians should only consider BMD testing and drug therapy for patients who are at higher risk for osteoporosis and fractures, not those who merely have Crohn’s disease as a diagnosis,” said Bernstein.

About the Study

Researchers from the University of Alberta in Canada conducted a randomized clinical trial of 150 patients who had Crohn’s disease and who attended either the Inflammatory Bowel Disease Referral Clinic (Alberta) or Mt. Sinai Hospital (Toronto). Study participants were classified into three groups following initial measure of BMD: normal bone density, osteopenia and osteoporosis. Patients with osteopenia and osteoporosis were then randomized to calcium and vitamin D supplementation or to etidronate plus calcium and vitamin D supplementation groups.

Advances in the Understanding and Treatment of Gastrointestinal Cancers

Colorectal Cancer: Bevacizumab Improves Survival, Oxaliplatin Reduces Recurrence; Pancreatic Cancer: Smoking Accelerates Development, Erlotinib Increases Survival; Rectal Cancer: Preoperative Radiation Reduces Recurrence

New research on the development and treatment of colorectal and pancreatic cancers was presented at a press conference at the 2005 Gastrointestinal Cancers Symposium, co-sponsored by the American Gastroenterological Association (AGA), the American Society of Clinical Oncology (ASCO), the American Society for Therapeutic Radiology and Oncology (ASTRO), and the Society of Surgical Oncology (SSO).

“These studies have major implications for our understanding and treatment of pancreatic and colorectal cancers,” said Robert J. Mayer, MD, Director of the Center for Gastrointestinal Oncology at Dana-Farber Cancer Institute and moderator of the press conference. “Some offer new hope for the prevention and treatment of pancreatic cancer, and others expand our options for treating colon and rectal cancers.”

(continued on page 108)
Studies include:

- A study reporting for the first time that pancreatic cancer patients who were smokers were diagnosed with the disease as much as 10 years earlier than nonsmokers.
- A phase III study from the National Cancer Institute of Canada showing that adding the targeted therapy erlotinib (Tarceva) to gemcitabine (Gemzar) increased survival among patients with advanced pancreatic cancer not previously treated with chemotherapy.
- A phase III multicenter study by the Eastern Cooperative Oncology Group reporting that bevacizumab (Avastin), given in combination with the FOLFOX4 chemotherapy regimen, improved overall survival by 17% among patients with advanced colorectal cancer that had been treated previously.
- Findings from the international MOSAIC trial, which showed that adding oxaliplatin to standard chemotherapy for early-stage colorectal cancer lowers the risk of recurrence.
- Findings from the Dutch Colorectal Cancer Group showing that while short-term radiation therapy before rectal cancer surgery decreases the risk of local recurrence, the treatment can have adverse effects in some patients.

Radiation Therapy for Prostate Cancer Nearly Doubles the Risk of Rectal Cancer

Men who undergo radiation for prostate cancer have nearly double the risk of developing rectal cancer when compared to men who opt to have surgery to treat prostate cancer, according to a study published in the April issue of *Gastroenterology*. Men who receive radiation for prostate cancer have a 70 percent higher risk of developing rectal cancer than those who underwent surgery, a risk similar to that posed by having a family history of the disease.

“Men who have had prostate radiation should be aggressively monitored for rectal cancer starting five years after treatment,” said Nancy Baxter, MD, PhD, lead study author with the University of Minnesota Cancer Center. “This is the first time rectal cancer risk associated with prostate radiation has been quantified, and these findings may also have implications for patients treated with radiation for other pelvic cancers.”

Prostate cancer is the most commonly diagnosed malignancy in the United States. Although there is a high rate of survival associated with prostate cancer, a large number of men are left at risk for long-term consequences of their cancer treatment, including the development of other cancers.

Researchers at the University of Minnesota Cancer Center used data from the Surveillance, Epidemiology and End Results (SEER) Registry to evaluate the effect of radiation on development of cancer in the rectum. More than 85,000 men, age 18 to 80, were included in this retrospective, population-based study. Radiation therapy for prostate cancer has been associated with an increased rate of pelvic malignancies, particularly bladder cancer. Findings of this study suggest that direct radiation to the rectum increases the risk of developing rectal cancer, but does not affect the risk of cancer in other parts of the colon.

“While the findings of our study do not suggest that prostate cancer treatment should change, we recommend that the potential for developing rectal cancer be included in conversations between doctors and patients when considering the individualized course of treatment and surveillance for patients with prostate cancer,” said Baxter.

Since the study results are based on men who were treated for prostate cancer prior to 1995, the risk of developing cancer may be reduced by the evolution of radiation delivery techniques. However, researchers say that even with today’s technology, some portions of the rectum might still receive a high dose of radiation. Therefore, the risk of rectal cancer may still be substantial and thus, until proven otherwise, men treated with radiation for prostate cancer need monitoring for rectal cancer beginning five years after treatment.

Guidelines of multiple agencies and professional societies underscore the importance of colorectal cancer screening for all individuals 50 years of age and older. Approved tests include barium enema, FOBT, flexible sigmoidoscopy and colonoscopy. However, flexible sigmoidoscopy and colonoscopy are the best methods for accurately detecting rectal cancer. Each screening option has advantages and disadvantages.
Patients undergoing radiation therapy for prostate cancer are advised to ask their doctor about one of the approved screening methods, regardless of their age.

More information about colorectal cancer screening is available at www.gastro.org.

CCFA is Announces BIG Changes to the Senior Research Awards

Effective for the July 1, 2005 submission deadline
Total Award: $143,000 per year for 3 years
Direct Costs: Up to $130,000
Indirect Costs: Up to 10% ($13,000) of direct costs

**Note: These new guidelines are not retroactive for existing awards.

Proposed research projects must be relevant to the inflammatory bowel diseases (Crohn’s disease and ulcerative colitis). Applicants must be established, independent researchers who hold an MD, PhD or equivalent degree and are employed by a public nonprofit, private non-profit, or government institution engaged in health care and/or health related research. Eligibility is not restricted by citizenship or geography.

Also Available:
• **Career Development Awards:** CCFA offers two types of training awards for young investigators who are employed by a public non-profit, private non-profit or a government institution engaged in health-related research within the United States and its possessions. Eligibility is not restricted by citizenship.

• **Clinical Research:** Total award not to exceed $90,000 per year for 3 years. This includes: Salary up to $52,000, fringe benefits up to 25% of salary ($13,000) and $25,000 to be used for tuition towards a Master of Public Health Degree (MPH) or equivalent. All clinical research applicants are required to complete this degree within the 3 year window of this award. If the researcher has already obtained an MPH degree, this money can be used for expenses related directly to the project.

• **Basic Research:** Total award not to exceed $90,000 per year for 3 years. This includes: Salary up to $52,000, fringe benefits up to 25% of salary ($13,000) and $25,000 for expenses related directly to the project.

• **Research Fellowship Awards:** Total award not to exceed $58,250 per year for 3 years. This includes: Salary up to $45,000, fringe benefits up to 25% of salary ($11,250), and $2,000 for expenses related directly to the project.

**Indirect costs are not allowed for Career Development Awards or Fellowship Awards.

Guidelines and application may be found on our website at www.ccfa.org.

Clinical Testing of the SmartPill Capsule is Set to Begin at Wake Forest University Baptist Medical Center

Wake Forest is a Leading GI Motility Research Center and the Third Clinical Trial Site to Come Online

Clinical trials of the SmartPill ACT-I Capsule and GI Monitoring System began at Wake Forest University Baptist Medical Center (Winston-Salem, NC) the week of April 18th, bringing to three the number of sites participating in the SmartPill 510(k) clinical trial.

A total of 25 subjects, 15 who are healthy and 10 who have been documented with gastroparesis, the inability of the stomach to empty, are expected to participate in the study. Kenneth Koch, M.D., who heads the Section on Gastroenterology at Wake Forest University Baptist Medical Center, will conduct the study as the principal investigator. The primary objective of the study is to demonstrate the correlation between the gastric residence times measured by the SmartPill ACT-I Capsule and by the ingestion of a radio-labeled meal and scintigraphic images.

The Wake Forest trial is expected to run 8–10 weeks, paralleling clinical trials now underway at Massachusetts General Hospital (Boston, MA) and Temple University Hospital (Philadelphia, PA). Additional clinical trial sites will be announced in the coming weeks, pending IRB approvals.

FDA Approves Intravenous Formulation for Nexium®

A new administration formulation for the prescription proton pump inhibitor Nexium® (esomeprazole magnesium) has been approved by the U.S. Food and Drug
Administration (FDA). Nexium IV is now approved as an intravenous infusion or injection for the short-term treatment (up to 10 days) of gastroesophageal reflux disease (GERD) patients, with a history of erosive esophagitis, who are unable to take capsules.

“Hospitalized patients with GERD are often unable to take their oral medication,” said David C. Metz, M.D., Professor of Medicine in the Division of Gastroenterology at the Hospital of the University of Pennsylvania. “The availability of Nexium in an intravenous formulation provides these patients with an effective alternative route of administration that they can tolerate easily.”

The approval of Nexium IV was based, in part, on the findings of four multicenter, open-label, two-period crossover studies. These studies compared the pharmacodynamic efficacy of the intravenous formulation with Nexium delayed-release capsules at corresponding doses of 20 mg and 40 mg in GERD patients with or without a history of erosive esophagitis. They demonstrated that, after 10 days of once-daily administration, Nexium IV 20 mg and 40 mg are similar in their ability to suppress acid to the corresponding oral dosage form of Nexium. There were no relevant changes in acid suppression when switching between intravenous and oral dosage form.

May Marks National Critical Care Awareness and Recognition Month

Patient Safety, Workforce Shortage to be Addressed

The month of May marks National Critical Care Awareness and Recognition Month. The Society of Critical Care Medicine (SCCM), partnering with the American Association of Critical-Care Nurses (AACN), American College of Chest Physicians (ACCP), American Thoracic Society (ATS), and the American Association for Respiratory Care (AARC) recognizes the devoted professionals whose compassion and dedication to the care of the critically ill and injured has made a significant difference in the lives of patients and their families.

At some point in their lives, nearly 80% of all Americans will suffer, or know someone who is suffering, from a life-threatening illness or injury. From heart attack and stroke, to burns and gunshot wounds, every day thousands of people suffer from critical conditions that place their lives in jeopardy.

In the rapid pace of the intensive care unit (ICU), each critical care practitioner must quickly obtain information, effectively convert it into knowledge, and then apply it to the best interests of the patients at the bedside. There are many ways to organize care within the ICU, but data show that optimal care is provided when an integrated team of dedicated experts is present to assess, initiate and adjust treatment to ensure that the best possible care is delivered to all critically ill or injured patients the moment it’s needed.

The core of this multiprofessional team consists of intensivists (physicians credentialed in critical care medicine), critical care nurses, pharmacists, respiratory therapists. Primary care physicians, physician assistants, social workers, dietitians, ethicists, consultant medical specialists, and other professionals are also often part of the team.