Swallowing a Tiny Imaging Capsule Aids in Diagnosis of Obscure Gastrointestinal Bleeding

The use of a small wireless capsule video device to detect bleeding in the small intestine is safe, well-tolerated, and more accurate than another common diagnostic approach according to a study presented at a meeting of the American College of Gastroenterology.

“The investigation of obscure gastrointestinal bleeding is often difficult due to limitations of conventional endoscopic studies in the detection of disorders in the small intestine,” said Ramona M. Lim, M.D., of the University of Miami School of Medicine/Mount Sinai Medical Center in Miami, FL.

Patients with obscure GI bleeding experience bleeding of unknown origin that persists or recurs after a negative initial endoscopy (colonoscopy and/or upper GI endoscopy). For some of these patients the bleeding may be caused by lesions in the small intestine that would not be detected with colonoscopy or upper GI endoscopy.

In wireless capsule endoscopy, the patient swallows a tiny imaging capsule that incorporates a light source, video camera, battery, antenna and radio transmitter. Images of the intestinal tract are transmitted twice each second by radio frequency to an array of sensors worn around the patient’s abdomen and the signals are digitally recorded on a device that is later downloaded. The patient swallows the capsule in the morning and wears the recording device for 8-hours. The capsule is eliminated and discarded. A gastroenterologist reviews the images.

Dr. Lim and her colleagues studied 20 patients with GI bleeding from an unidentified source. Researchers evaluated these patients using the wireless capsule technology, then followed up using a technique known as push enteroscopy. In push enteroscopy, a four-foot long tube outfitted with a small video camera is inserted down the esophagus, through the stomach and into the first third of the small intestine. The researchers found that wireless capsule endoscopy identified potential sources of bleeding in 70 percent of the patients, compared to 45 percent with push enteroscopy.

While the Miami study revealed that this technology is more sensitive than push enteroscopy in detecting problems in the small intestine, it is not without drawbacks. With wireless capsule endoscopy a gastroenterologist cannot biopsy or treat pathologies in the small intestine. The use of this technology is not appropriate for patients with bowel obstructions. The M2A capsule is manufactured by Given Imaging.

Treating Acid Reflux Reduces Asthma Symptoms and Improves Quality of Life in Patients with Asthma

The daily use of medications to treat acid reflux, proton pump inhibitors (PPI), reduces asthma exacerbations and improves general well-being of asthma patients with symptoms of acid reflux. A study presented at the annual scientific meeting of American College of Gastroenterology found that the use of a proton pump inhibitor along with asthma medications improved reflux symptoms, as well as improving reported quality of life. Fewer patients taking PPIs had at least one asthma exacerbation with PPI vs. placebo.

In this multicenter, randomized, double-blind, placebo-controlled study, 207 subjects receiving usual asthma care were randomize to 30 mg twice a day of lansoprazole or placebo. All subjects had symptoms of acid reflux, moderate to severe persistent asthma, and were taking inhaled corticosteroids.

According to Michael R. Littner, M.D., one of the investigators from the Veterans Administration Healthcare System in Sepulveda, CA, the use of a proton pump inhibitor “appears to offer the most benefit to asthma patients with more difficult to control asthma as indicated by the requirement for more than one long-term asthma control medication.”

New Findings Support Benefits of Women Having Screening Colonoscopy at 50

For people with average risk, the American College of Gastroenterology recommends screening colonoscopy (continued on page 43)
(continued from page 40)

every 10 years beginning at age 50. Although it is thought that women may develop colorectal polyps later than do men, a new study suggests there is no evidence to support revising the screening guideline from age 50 to age 60 for women. An analysis of data from 1,328 consecutive women who had a screening colonoscopy for colorectal cancer revealed that the proportion of women in their fifties who had polyps was nearly as high as the proportion of women in their sixties who had polyps.

“Nearly all colorectal cancers develop from adenomatous polyps, and these polyps have malignant potential. Thus, most colorectal cancers can be prevented by removing these premalignant polyps from the body,” said Philip S. Schoenfeld, M.D., of the University of Michigan (Ann Arbor). “Our analysis demonstrated that women 50–59 years old and women 60–69 years old had similar prevalence of colon polyps.”

Dr. Schoenfeld and colleagues from other institutions—the Uniformed Services University of the Health Sciences (Bethesda), National Cancer Institute (Bethesda), and Oregon Health Sciences University (Portland)—compared colonoscopy results for asymptomatic women aged 50 to 59 and aged 60 to 69. Women were excluded from the study if they reported having a colonoscopy or barium enema within the last 10 years, or flexible sigmoidoscopy within the last 5 years. The researchers also excluded women with iron deficiency anemia or blood in the stool within the past year. Adenomas (polyps with malignant potential) were found in 18 percent of women aged 50 to 59 and in about 21 percent of women aged 60 to 69. Schoenfeld and colleagues say the difference in prevalence does not appear to be clinically significant.

**Fructose Intolerance Could Be the Culprit in Unexplained Abdominal Pain and Gas**

Researchers Recommend Testing Symptomatic Patients for the Condition

Researchers at the University of Kansas Medical Center (Kansas City) urge physicians to consider adding fructose breath testing to their diagnostic strategy for patients with unexplained abdominal pain, gas, diarrhea, and intestinal rumbling or gurgling. The recent study’s results, indicate that fructose malabsorption occurs in a significant proportion of healthy adults.

Fructose—the simple sugar found in honey, many fruits, and some soft drinks—is one of the principal sweeteners in the Western diet. Not everyone has the ability to absorb fructose properly, however, and now researchers are discovering that it may play an important role in the onset of common gastrointestinal symptoms, such as bloating, cramps, and diarrhea. These symptoms arise when the fructose is allowed to pass through the digestive tract to the colon, where some bacteria can use the sugar as a food source. Unfortunately, in the process, hydrogen gas is liberated.

After the subjects were given 25 grams of fructose, which is about how much is in a 12-ounce can of soda sweetened with high fructose corn syrup, the researchers collected breath samples. The analysis revealed an abnormal level (greater than 20 parts per million) of hydrogen gas in nearly one-half of the subjects. Hydrogen gas would not be present in breath unless fructose was not digested normally. On a subsequent day, the subjects received 50 grams of fructose, and about three-quarters had hydrogen levels greater than 20 parts per million.

“When given levels of fructose commonly consumed in the Western diet, a significant number of our subjects had both objective and subjective evidence of fructose malabsorption, meaning that the breath analysis showed hydrogen in excess of 20 parts per million and they had symptoms like gas and diarrhea,” said Peter Beyer, M.S., R.D., of the Dietetics and Nutrition Department at the University of Kansas Medical Center. “When patients present with such symptoms, doctors should consider adding breath analysis for fructose intolerance to the arsenal of routine diagnostic tests.”

Last year, at ACG’s 66th Annual Scientific Meeting, Young K. Choi, M.D. and colleagues from the University of Iowa performed fructose breath tests on 219 patients with unexplained gas, bloating, and pain. The analysis revealed the abnormal presence of hydrogen or methane gas in 78 percent of the patients and gastrointestinal symptoms in 58 percent.

“If a patient is found to be fructose intolerant and symptomatic, the doctor may recommend a low-fructose diet,” said Beyer. “But in severe cases, antibiotic therapy may be required to provide relief.”
Costs for Surgical Treatment of GERD Not Offset by Savings on Medications
Researchers Discover that Surgery Does Not Eliminate Use of Acid Reduction Therapy

A recent study shows that although people with GERD experienced a 62 percent decline in the average number of days of acid reduction therapy after surgery, one-half of patients received at least one prescription for acid reduction therapy during the 18 months following surgery. More than 15 million Americans experience daily heartburn symptoms and may suffer from GERD.

“To assess the economic implications of medical versus surgical management of GERD, we analyzed medical costs for patients one year before and 18 months after surgery,” said the study’s lead author Erin M. Sullivan, Ph.D., of the Boston Scientific Corporation (Natick, MA). “The assumption has been that the one-time cost of surgery is lower than the long-term cost of drugs, but we found that the surgery costs were not offset by the reduction in medication costs during an 18-month follow-up period,” said Dr. Sullivan.

The symptoms of GERD are caused when the valve between the stomach and esophagus allows stomach acid to leak into the esophagus. Some people with GERD opt for surgery when drugs do not help enough or when they want to avoid taking drugs for the rest of their lives. When surgery is successful, the one-way valve between the esophagus and stomach works and GERD symptoms reportedly improve. The researchers examined data from a national database of publicly and privately insured patients. The records of 123 surgical patients were matched to the records of 246 GERD patients managed without surgery. Patients were matched according to age, sex, and other factors.

Slightly more than one-half (54 percent) of patients were female, and the average age of the subjects was 48 years. To control for inflation, Sullivan and colleagues converted all medical costs to 2001 U.S. dollars.

“During the 18 months following surgery, average medication costs were lower in surgically managed patients compared to medically managed patients. However, due to the surgery costs, overall medical costs were higher among surgically managed patients,” said Dr. Sullivan. “Our results indicate that we need to follow GERD patients over a longer follow-up period to determine the actual cost-effectiveness of surgery.”

New Study Documents Burden of Irritable Bowel Syndrome for U.S. Sufferers

Results of a survey of patients with irritable bowel syndrome in the United States reveal a substantial burden on patients, including decreased quality of life, high out-of-pocket costs, and losses in productivity among other findings.

IBS is a cluster of symptoms consisting commonly of abdominal pain, bloating, constipation and diarrhea. Some IBS patients experience alternating diarrhea and constipation. IBS is a functional disorder of the intestine. There is no sign of the disease that can be seen or measured, but the intestine is not functioning normally. It is common, occurring in about one in five Americans, more commonly in women. It usually begins in late adolescence or early adult life and rarely appears for the first time after the age of 50.

A survey mailed to 1,340 members of a national patient advocacy organization representing those with irritable bowel syndrome resulted in 657 responses. The survey, developed by Mugdha Gore, Ph.D. of Avalon Health Solutions on behalf of Novartis Pharmaceuticals Corporation, solicited information on patient demographics, disease history, symptom frequency and bothersomeness, health care utilization, medication use, out-of-pocket expenses, and impact of symptoms upon productivity and functioning.

Of the respondents, 65% met accepted criteria for IBS (Rome II). Of these, 95% were white, 79% female, and 58% single. Their mean age was 54 and mean age at IBS diagnosis was 41 years. Among those with IBS, 99% experienced one or more GI symptom during the past 3 months, and two-thirds of IBS patients experienced 10 to 24 GI symptoms during this time. Almost all (97%) had two or more consults with a health care professional for their GI disorder in the last three months, and 75% had four or more consults (visits and telephone calls.)

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The use of multiple over-the-counter (OTC) and prescription medications and alternative therapies was common: 89% reported taking at least three therapies (1 Rx, 1 OTC and 1 alternative.) Over 40% reported taking two or more of each Rx (57%), OTC (47%) and alternative therapies (43%). Patients spent an average of $258 for their GI disorder during the past three months, according to the survey findings.

Of IBS patients who work, 39% reported missing work and decreased productivity an average of 6 days and 16 days respectively, and decreased productivity at home an average of 16 days in the last three months. Ninety percent reported limited ability to perform important daily activities due to their GI disorder.

**Combination Therapy with Pegylated Interferon A Plus Ribavirin Effective for Refractory Hepatitis C Infection**

A study of a new combination therapy for patients with Hepatitis C infection who had failed to respond to the drug ribavirin alone, presented by researchers from the Naval Medical Center in San Diego and the University of California San Diego Medical Center, found that among those patients who previously failed to respond to ribavirin, treatment with a combination of pegylated interferon alpha-2-b with ribavirin for 48 weeks achieved viral response for 34 percent of study participants. Of the 178 patients enrolled in this randomized, open-labeled trial, 77 completed 48 weeks of therapy.

“This is interim data, but if the final results are as encouraging as the interim analysis, re-treatment with pegylated interferon alpha-2-b and ribavirin should be recommended for patients with chronic hepatitis C infection previously refractory to therapy with ribavirin,” said Chris B. Hyun, M.D. of the Naval Medical Center in San Diego.

According to the Centers for Disease Control & Prevention, an estimated 3.9 million (1.8 percent) Americans have been infected with HCV, of whom 2.7 million are chronically infected. Among those with chronic hepatitis C infection, fifteen to twenty percent will eventually develop cirrhosis of the liver. The Food and Drug Administration recently approved pegylated interferon alpha-2-b (Schering’s PEG-Intron).

**GERD and Other GI Disorders May Disrupt Sleep**

*Two Studies Measure Impact of Sleep Disturbances*

The results of two recent studies suggest that people with GERD (gastroesophageal reflux disease) and other gastrointestinal disorders are more likely than others to report excessive daytime sleepiness, insomnia, and poor sleep quality. More than 15 million Americans experience daily heartburn symptoms and may suffer from GERD.

**Excessive Daytime Sleepiness**

Researchers at Pennsylvania State University (Hershey) conducted a large study using records from a random telephone survey of 16,583 adults. From this pool, 1,741 adults who reported having risk factors for sleep-related breathing disorders were selected for further study. After undergoing a physical examination and providing a detailed medical history, each subject spent a night in the sleep lab.

“Our study is different from most others in that we did not base the analyses on subjects who were recruited because they had specific gastrointestinal disorders. After removing this selection bias from the equation, we can be more confident when we report that there is a significant relationship between GERD and excessive daytime sleepiness and insomnia,” said Geoffrey S. Raymer, M.D., of the Gastroenterology and Hepatology Department at Penn State. “We also found a connection between peptic ulcer disease and hiatal hernia and insomnia.”

The 1,741 adults selected for this study also were the subject of a recent analysis of insomnia and physical and mental health problems. The results were published by the Penn State researchers in the July 2002 issue of the Journal of Psychosomatic Research 53(1):589-592.

**Objective Measures of Sleep vs. Complaints**

William C. Orr, Ph.D., and Jennifer J. Thompson of the Lynn Health Science Institute in Oklahoma City compared data from 20 GERD patients with results from their database of healthy individuals. All the GERD patients reported having heartburn at least four days per week and having woken up with heartburn at least one night a week. The participants completed the
Pittsburgh Sleep Quality Index exam and underwent a baseline esophageal monitoring evaluation for 24 hours. In the sleep lab, they also underwent full polysomnography (comprehensive and continuous monitoring of physiology during sleep), which evaluated the number of minutes required to fall asleep, the number of arousals from sleep, sleep efficiency, and the proportion of time spent in various stages of sleep.

People with GERD reported having much worse sleep quality than did healthy adults. The difference between the two groups for this subjective measure was statistically significant (P < 0.05.) Among people with GERD, higher levels of reflux during the day are associated with more complaints about sleep.

“There is very little data in the literature that compare objective and subjective sleep measures among people with GERD,” said Dr. Orr. “Although our study establishes that there is a difference between GERD patients and healthy adults for subjective measures of sleep quality, our findings indicate that the objective measures were not appreciably different between the two groups.”

Smoking Found To Be an Important Risk Factor for Colorectal Polyps
Researchers Recommend Screening Smokers at an Earlier Age

Stony Brook University, N.Y., researchers have identified smoking as a key risk factor for colorectal polyps. Rajeev Attam, M.D., and colleagues analyzed the medical records of 1,566 consecutive patients who had a screening colonoscopy, and they found that the incidence of polyps was higher among current smokers than ex-smokers or non-smokers. Ex-smokers were defined as people who had quit more than 10 years ago but had smoked for more than 10 years.

“It is well established that family history of colon cancer is predictive of colorectal polyps, but our statistical analysis indicates that being a current smoker is equally predictive,” said Dr. Attam, the lead author of the study. “Polyps were found in about 19 percent of ex-smokers and about 17 percent of non-smokers, whereas 25 percent of smokers had polyps.”

The Stony Brook scientists collected data for 354 smokers, 364 ex-smokers, and 848 non-smokers who had a screening colonoscopy between December 1999 and April 2002. In addition to noting the colonoscopy results, the researchers examined data for age, sex, family, and personal history of colon cancer, smoking habits, alcohol and wine consumption habits, fruit and vegetable intake, body mass index, weekly exercise habits, and history of inflammatory bowel disease.

“Perhaps an even more important finding is that a much larger proportion of the smokers had more than two polyps, had a polyp larger than 1 centimeter, or had a polyp with a greater potential for malignancy. These differences had high statistical significance,” said Dr. Attam. “Although current guidelines recommend that people with average risk start screening colonoscopy at age 50, our results suggest that physicians should consider performing screening colonoscopy in current smokers before age 50.”

A GUIDE FOR PATIENTS

The more that a patient knows about his or her problem, the easier it is for the patient to cooperate with you and the more effective can be the prescribed treatment. Each “Guide” is on a different subject among the digestive diseases. You may cut out the “Guide” and photocopy as many reprints as you wish for distribution to your patients. You may want to include your name and address. The information in “A Guide for Patients” has been prepared by the National Digestive Diseases Information Clearing House, a service of the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, U.S. Public Health Service. The material it contains has been carefully reviewed by NDDIC for scientific accuracy and content.

This month’s “A Guide for Patients” appears on pages 58–61.

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FDA Approves Pegasys® (peginterferon alfa-2a)
For the Treatment of Hepatitis C
Roche sample program to provide first 12 weeks of
Pegasys at no cost for up to 15,000 patients

Roche announced that the U.S. Food and Drug Admin-
istration (FDA) has approved Pegasys® (peginterferon
alfa-2a) for the treatment of adults with chronic hepato-
is C who have compensated liver disease and have not
previously been treated with interferon alpha. Patients
in whom efficacy was demonstrated included patients
with compensated cirrhosis.

Pegasys is a pegylated interferon that remains active
in the bloodstream longer and at a more constant level
than interferon alpha. Currently, 2.7 million Americans
are chronically infected with hepatitis C.

“The approval of Pegasys is an important milestone
for the hepatitis C patients in the United States who are
waiting for treatment,” said George B. Abercrombie,
President and Chief Executive Officer, Hoffmann-La
Roche Inc. “Roche has supported Pegasys with the most
extensive development program ever undertaken for a
hepatitis C treatment. The result is that patients and
physicians have an important new option for treatment.”

Pegasys was granted approval based on the results
of three pivotal Phase III clinical trials that demon-
strated it is an effective treatment for patients with
chronic hepatitis C, including cirrhotic patients with
compensated liver disease, versus treatment with
Roferon-A® (interferon alfa-2a). Two of these pivotal
trials were published in The New England Journal of
Medicine.

The sustained virological response rate in the
Pegasys treated patients was as high as 38 percent in the
overall population versus 19 percent in the interferon
alfa-2a group. The sustained virological response in
patients with cirrhosis treated with Pegasys was as high
as 30 percent versus 8 percent in the interferon alfa-2a
group. Higher sustained virological response results
were also found in patients with genotype 1, on Pegasys
treatment (23 percent) versus interferon alfa-2a (6 per-
cent), the most common type in the U.S. and most diffi-
cult to treat. Sustained virological response was defined
as undetectable serum hepatitis C RNA levels post-
treatment (on or after study week 68).

Clinical trials of Pegasys have shown that patients
can determine at 12 weeks if they are unlikely to attain
a sustained virological response with Pegasys.

Pegasys investigator, Donald Jensen, MD, director
of Hepatology at Rush-Presbyterian-St. Luke’s Medical
Center, Chicago said, “With Pegasys, we can determine
at week 12 of therapy those patients who are unlikely to
achieve a sustained virological response to treatment.
This reduces the cost and burden of taking therapy for
patients who are unlikely to respond to therapy.

This may help patients adhere to therapy that can be
difficult on them, particularly during the first few months.”

12-Week Sample Program for
Up to 15,000 Patients

As part of Roche’s commitment to treating patients with
hepatitis C, Roche will be providing physicians with
samples of Pegasys for the first 12 weeks of therapy.
These samples will be provided at the request of a
physician for the first 15,000 patients who are started on
Pegasys therapy prior to December 31, 2002. Twelve
weeks was selected because at that point physicians can
predict those patients who will not respond to Pegasys
therapy. Samples are available to all physicians.

Pegasys, available as a premixed solution, is
expected to be in pharmacies within two weeks. Pegasys
is dosed at 180 µg as a subcutaneous injection once a
week for a recommended duration of 48 weeks.

Pegasys is supported by the most extensive de-
velopment program ever undertaken for a hepatitis C treat-
ment. The FDA has granted Pegasys in combination
with Copegus® (Roche ribavirin) priority review status,
and a decision is expected by the end of 2002. The FDA
grants priority review status to products that, if
approved, are expected to offer a significant improve-
ment over existing therapies in the safety or effective-
ness of the treatment, diagnosis or prevention of a seri-
ous or life-threatening disease.

Pegasys has been studied in a variety of patient pop-
ulations, including those with the most difficult to treat
form of the disease—patients with genotype 1 and with
cirrhosis (scarring of the liver).

Pegasys is made when interferon alfa-2a undergoes
the process of pegylation in which one or more chains

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of polyethylene glycol, also known as PEG, are attached to another molecule. In Pegasys, a large, branched, mobile PEG is bound to the interferon alfa-2a molecule and provides a selectively protective barrier. Pharmacokinetic behavior of the end product depends on the length of the PEG and the nature of the link between the PEG and the protein. The high molecular weight (40 kilodalton) branched PEG in Pegasys has been shown to provide sustained pegylated interferon alfa-2a exposure at clinically effective levels over the one-week dosing period.

In contrast, interferons with smaller PEGs are excreted more rapidly by the kidneys, requiring more frequent dosing, according to earlier Roche studies, using smaller PEGs developed by the company.

Pegasys has been approved for use in 50 countries, including all European Union countries.

Alpha interferons, including Pegasys, may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Patients with persistently severe or worsening signs or symptoms of these conditions should be withdrawn from therapy. In many, but not all cases, these disorders resolve after stopping Pegasys therapy.

Pegasys is contraindicated in patients with hypersensitivity to Pegasys or any of its components, autoimmune hepatitis, and decompensated hepatic disease prior to or during treatment with Pegasys. Pegasys is also contraindicated in neonates and infants because it contains benzyl alcohol. Benzyl alcohol has been reported to be associated with an increased incidence of neurological and other complications in neonates and infants which are sometimes fatal.

The most common adverse events reported for Pegasys, observed in clinical studies to date, were headache, fatigue, myalgia, pyrexia, rigors, arthralgia, nausea, alopecia, injection-site reaction, neutropenia, insomnia, depression, anorexia, and irritability.

Other serious adverse events include bone marrow toxicity, cardiovascular disorders, hypersensitivity, endocrine disorders, pulmonary disorders, colitis, pancreatitis, and ophthalmologic disorders.

The complete package insert is available upon request.

University of Virginia Health System Nutrition Support Traineeship Program

The University of Virginia Health System is offering a Nutrition Support Traineeship Program. The five-day program will provide trainees with the opportunity to achieve a higher level of practice in nutrition support. The program goal is to optimize continuing education time and expenses by focusing on the individual RD’s (nutritionist’s) learning needs. This evidence-based program utilizes actual patient cases, physician-led NST rounds, small group discussions, critical evaluation of research, and a practical, hands-on approach to learning. Also included is an elaborate, fully referenced syllabus.

• Basic Program includes:
  – Nutritional Assessment
  – Critical Care
  – Parenteral Nutrition
  – Enteral Feeding
  – Determining calorie/protein requirements
  – Home Care
  – Monitoring/addressing metabolic effects of nutrition support

• Optional Experiences available:
  – GI Clinics/Outpatient PEG Program
  – GI issues
    - Celiac Disease
    - Malabsorption/Short Bowel Syndrome
    - Pancreatitis
    - Hepatic disease
    - Gastroparesis
    - Oral Rehydration Therapy
  – Surgery/Trauma

• Faculty:
  Carol Rees Parrish, RD, MS
  Joe Krenitsky, MS, RD
  Nutrition Support Specialists
  Digestive Health Center of Excellence
  University of Virginia Health System
  Charlottesville, VA

• For More information: Contact Linda Niven by phone (434) 924-2286 or e-mail ltn6m@virginia.edu
Solvay Pharmaceuticals, Inc. Awards 20 College Scholarships to Students with Cystic Fibrosis Program Celebrating Its 10th Anniversary

Solvay Pharmaceuticals, Inc. has selected 20 students with cystic fibrosis (CF) to receive a CREON® MINIMICROSHERES® (Pancrelipase Delayed-Release Capsules, USP) Family Scholarship. These winners are being recognized for their triumph over CF, an incurable genetic disease. Each student will receive $2,000 per year for up to four years of study and a year’s supply of CREON® MINIMICROSHERES®.

Now in its 10th year, the Family Scholarship program is funded by Solvay Pharmaceuticals. Scholarships are awarded to students based on academic achievement, financial need, leadership qualities and ability to serve as a role model to others with CF. All U.S. citizens with CF who are high school seniors, vocational school students or college students are eligible to apply. Applications are available at CF treatment centers nationwide each year from March through June. Since the program’s inception, the company has awarded 200 scholarships totaling more than $1.2 million.

Solvay Pharmaceuticals established the Family Scholarship program in 1993 as part of its Partners in CaringSM program. Partners in CaringSM provides education and support for patients and families affected by CF as well as to care providers at CF treatment centers across the United States. Solvay Pharmaceuticals markets the pancreatic enzyme supplement CREON® MINIMICROSHERES® Capsules. Cystic fibrosis is a genetic disease affecting approximately 30,000 children and Young adults in the United States. CF causes digestive and chronic lung problems that require frequent therapy.

First Seven-Day Treatment of H. Pylori Infection Approved by FDA

Aciphex® (rabeprazole sodium) Plus Antibiotics Faster Than Currently Approved Options

Aciphex (Eisai/Janssen), a proton pump inhibitor (PPI) widely prescribed for gastroesophageal reflux disease (GERD), is now approved by the Food and Drug Administration as part of the first seven-day treatment for Helicobacter pylori (H. pylori) infection, the single most common cause of peptic ulcers. Taken in combination with certain antibiotics, Aciphex offers a faster therapy option than other PPIs, treating H. pylori in up to half the time of current 10 to 14 day treatment.

When used in combination with amoxicillin and clarithromycin as a three-drug regimen, Aciphex is indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history within the last five years) to eradicate H. pylori.

Up to 60 million American adults are currently infected with H. pylori; as many as one in 10 Americans will develop an ulcer in their lifetime.

“Using Aciphex, plus antibiotics for one week to eradicate H. pylori is a faster treatment option than what is currently available,” said Nimish Vakil, M.D., Clinical Professor of Medicine at the University of Wisconsin Medical School, Milwaukee, WI. “When you consider the fact that the majority of duodenal and gastric ulcers are caused by H. pylori infection and that a short treatment course eradicates the infection and prevents relapse, you can understand the importance of this infection in ulcer disease.”

A multicenter, double-blind, placebo-controlled trial was conducted in 803 patients infected with H. pylori at 47 centers nationwide. In the study, 84 percent of patients treated with Aciphex (rabeprazole sodium), amoxicillin and clarithromycin taken twice daily were free of H. pylori after seven days of therapy. Eight-six percent of patients taking the identical regimen achieved the same result after 10 days of treatment, with no significant difference obtained with three additional days of therapy. H. pylori was eradicated in 82 percent of patients treated with a combination of omeprazole, amoxicillin and clarithromycin taken twice daily for 10 days based on per protocol analysis. The three-day Aciphex, amoxicillin and clarithromycin treatment arm was clinically sub-optimal for H. pylori eradication. Eradication of bacteria was determined by a negative Urea Breath Test (13C-UBT) at 42 or more days after the end of therapy.

In clinical trials using combination therapy with rabeprazole plus amoxicillin and clarithromycin (RAC), no adverse events unique to their drug combination were observed. In the U.S. multicenter study, the most frequently reported drug related adverse events for patients who received RAC therapy for seven or ten days were diarrhea (8 percent and 7 percent) and taste perversion (6 percent and 10 Percent) respectively.

No clinically significant laboratory abnormalities particular to the drug combinations were observed.
Symptoms of Achalasia

The symptoms and radiographs of 38 patients with confirmed achalasia were reviewed, 20 prospectively and 18 retrospectively. The number of typical and atypical symptoms, both initially and at the time of the barium esophagram were tallied and were scored on a point system. Dysphagia was the initial symptom in only 39 percent, whereas heartburn, regurgitation and slow eating occurred initially in 24 percent, 24 percent, and 16 percent of patients, respectively.

The median time period between initial symptoms and symptoms that progressed and were reported at the time of barium esophagram was 48 months. At the time of the esophagram, the most frequently reported symptoms were slow eating (79 percent), followed by dysphagia (76 percent) and stereotype movements, including arching of the neck and shoulders or other positional circumstances for swallowing with meals (60 percent).

It was interpreted that achalasia is a disease with many atypical and subtle symptoms, both initially and over time. Dysphagia is initially present in only 39 percent of patients and had not been the most frequently reported symptom over time. Neither the severity nor total number of achalasia-related symptoms correlated with the severity of the radiographic findings. (Blam ME, Delfyett W, Levine MS, et al. “Achalasia: A Disease of Varied and Subtle Symptoms That Do Not Correlate With Radiographic Findings.” American Journal of Gastroenterology, 2002; Vol. 97, pp. 1916-1923.)

Treatment of Intractable Pruritus In Cholestasis

Three patients were evaluated for plasmapheresis because of intractable cholestatic-related pruritus. All had been treated with standard therapies, including diphenhydramine, chlorpheniramine, cholestyramine, rifampicin, phenobarbital, doxepin, naltrexone, ultraviolet therapy and topical lotions. Multiple courses of plasmapheresis were performed without benefit. All patients reported significant decrease in quality of life, including lack of sleep, depression, inability to work and suicidal ideations. All patients were started on 5mg of Marinol at bedtime (Delta 9-Tetrahydrocannabinol). All three patients reported a decrease in pruritus, marked improvement in sleep and were eventually able to return to work. Resolution of depression occurred in two of three patients. Side effects included incoordination in one patient and decrease of dosage to 2.5mg was accomplishable in one patient. The duration of the antipruritic effect was approximately 4 to 6 hours, so that more frequent dosing may be required. (Neff GW, O Brien CD, Reddy KR, et al. “Preliminary Observation With Dronabinol in Patients With Intractable Pruritus Secondary to Cholestatic Liver Disease.” American Journal of Gastroenterology, 2002; Vol. 97, pp. 2117-2119.)

HCV Genotype 3 and Steatosis

Twenty-eight patients with genotype 1 and 34 with genotype 3 HCV were evaluated, evaluating the severity of steatosis in pre- and post-treatment liver biopsies. Before treatment, hepatic steatosis was present. 57 patients were infected with HCV genotype 1 and 62 percent of those were genotype 3. Sustained viral response was achieved with treatment in 32 percent of patients with genotype 1 and 65 percent with genotype 3. In neither group were there significant changes in body weight or alcohol consumption between pre- and post-treatment biopsies.

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(continued from page 52)

In patients with HCV genotype 1, there was no change in hepatic steatosis after treatment, irrespective of the treatment response. Among those infected with genotype 3, SVR significantly reduced steatosis, but there was no change in steatosis among those without a sustained viral response. Data was interpreted as providing strong report for direct causal association between HCV genotype 3 infection and hepatic steatosis. (Kumar D, Farrell GC, Fung C, George J. “Hepatitis Virus Genotype 3 is Cytopathic to Hepatocytes: Reversal of Hepatic Steatosis After Sustained Therapeutic Response.” Hepatology, 2002; Vol. 36, pp. 1266-1272.)

Risk Factors for HCC

A hospital-based, case-controlled study among 115 HCC patients and 230 non-liver cancer controls was conducted. Risk factor information was collected by personal interview and medical record review. Blood samples were tested for the presence of antibodies to hepatitis C virus antigen, hepatitis B surface antigen and antibodies to hepatitis B core antigen. Information collected included heavy alcohol consumption and diabetes mellitus, respectively.

Synergistic interactions on the additive model was observed between heavy alcohol consumption and chronic hepatitis virus infection and diabetes mellitus. Independent of HCV, HBV and diabetes mellitus, heavy alcohol consumption contributes to the majority of HCC cases (32 percent), whereas 22 percent, 16 percent and 20 percent were explained by HCV, HBV and diabetes mellitus, respectively.

It was concluded that the significant synergy between heavy alcohol consumption, hepatitis virus infection and diabetes mellitus may suggest a common pathway for hepatocarcinogenesis. (Hassan MM, Hwang LU, Hatten CJ, et al. “Risk Factors for Hepatocellular Carcinoma: Synergism of Alcohol With Viral Hepatitis and Diabetes Mellitus.” Hepatology, 2002; Vol. 36, pp. 1206-1213.)

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Chronic Viral Hepatitis; Diagnosis and Therapeutics
Koff RS and Wu GY (eds)
Humana Press, Totowa, New Jersey

Drs. Koff and Wu set out to construct a contemporary comprehensive overview of the field of chronic viral hepatitis. They gathered together 16 well-researched, well-written chapters by 14 pre-eminent senior hepatologists, and 16 associates. References are abundant, and emphasis on higher quality published research is employed throughout. In a few chapters I could find mainly older references, but in most chapters citations right up to the publication year are included.

Important topics in chronic viral hepatitis are dealt with in great detail. Some of the more difficult areas (HIV/HCV and HBV/HCV co-infections, autoimmune disease, and chronic viral hepatitis) were fully and satisfyingly developed. The chapter on Natural History of Hepatitis C is one among many that stand out as an excellent creation. The range of possible outcomes, including data from Irish and East German experiences with known-source HCV infection, indicates a spontaneous recovery rate of 45%, far higher than most often cited figures. The chapter on complementary and alternative treatment of liver disease contains a succinct history of non-traditional medicine. It provides an even-handed evidence-based discussion of the use of herbs, such as milk thistle, in chronic liver disease.

Other areas of substantial interest to many, such as renal involvement, and liver pathology were given scant treatment. There is little about hepatitis B or C in children. The index was of variable quality. Although no chapter is devoted to iron in chronic viral hepatitis, the index provides guidance to three areas where this topic is beautifully developed and well-referenced. On the other hand, an index-search for leukocytoclastic vasculitis, or membranoproliferative glomerulonephritis yielded nothing. Certain production errors are apparent in my edition. Chapter 9 (Treatment of Chronic Viral Hepatitis in Patients With Autoimmune Disease) has a header on each page identifying a different chapter (Treatment of Chronic Viral Hepatitis in AIDS Patients). In the text are a few phantom references. In short, it appears that the rush to get this book to print precluded full development and product quality control.

The field is changing so rapidly, that any editor must deal with the frustration of having an instantly dated work. Since September, 2001, we have seen a NIH Consensus Conference on Hepatitis C, FDA-approval of adefovir for chronic viral hepatitis B, establishment of a regimen of pegylated interferon and ribavirin as the best approach to hepatitis C, and of useful 12-week stopping rules for genotype 1 hepatitis C treatment. These topics are either not mentioned or given cursory treatment in the relevant chapters.

I like this book and value it in my library. I suspect most medical libraries will want a copy. It should also be considered for all GI and Hepatology training programs. The authors have achieved their goal and are to be congratulated. The book list retail price is US$99.50. It is available for US$ 89.00 from the publisher’s website (www.humanapress.com).

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