

# Gastroenterology & Endoscopy News

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## New Options Evaluated for Infliximab-Refractory IBD

By Steve Frandzel

LAS VEGAS—Until recently, the frontier of medical treatment for patients with moderate to severe Crohn's disease (CD) was occupied by a lone biologic—infliximab (Remicade, Centocor); however, physicians may soon have several new options to consider. These new medical developments are particularly relevant for the more than 30% of CD patients who respond to infliximab initially but whose response to the drug wanes over time,

Found in Translation

see [Biologics](#), page 56

## Zelnorm Withdrawn After Safety Evaluation

By Steve Frandzel

Complying with a request from the FDA, Drug maker Novartis has suspended U.S. marketing and sales of tegaserod (Zelnorm), used to treat women with constipation-dominant IBS and men and women with chronic constipation. The action was taken after the company notified the FDA that a retrospective analysis of clinical trial data revealed a higher-than-expected incidence of cardiovascular adverse events.

FDA Update & Product News

see [Zelnorm](#), page 82

## New Study Highlights Need for Proper Screening For Celiac Disease in Patients With GI Symptoms

*Expert Calls for Increased Physician Awareness, Education*

By Rosemary Frei, MSc

A new study demonstrates a 43-fold increase in the detection rate of celiac disease, from 0.27 to 11.6 cases per 1,000 visits, with proper screening of all patients who have suggestive symptoms (Catassi C et al. *Am J Gastroenterol* 2007; Mar 13 [E-pub ahead of print]). Lead investigator Alessio Fasano, MD, and his team contend that such screening should be done because it would improve patient quality of life and reduce the amount of treatment—and hence healthcare-related costs—of patients who develop complications from undiagnosed celiac disease.

In addition, two studies presented at the 2007 Canadian Digestive Diseases Week (CDDW) meeting, one of which showed the majority of cases of celiac disease are not detected due to the use of a non-effective screening protocol, concluded that there is an urgent need to increase physician awareness and diagnosis of celiac disease. These studies come on the heels of a survey indicating that, at least in Canada, the mean delay between symptom onset and diagnosis of celiac disease is 11.7 years (Cranney A et al. *Dig Dis Sci* 2007;52:1087-1095).

"I think both the National Institutes of Health and

see [Celiac](#), page 8



## Accreditation of Office-Based Endoscopy On the Rise in New York, Elsewhere

By Monica J. Smith

NEW YORK CITY—The push toward accreditation for office-based endoscopy is on the rise in New York and several states around the country to assure that office-based practices perform at the same level demanded of hospitals and ambulatory surgical centers (ASCs). A costly, time-consuming endeavor, the process of becoming accredited can be viewed as a burden. It can also result in considerable financial gain.

"It depends on the roster of patients you have and who your carriers are, but I

see [Accreditation](#), page 24



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#### PRODUCT ANNOUNCEMENT

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**The EPK-i system from Pentax** offers 50% higher resolution than other endoscopes



#### PRODUCT ANNOUNCEMENT

see page 81 for product information

**QuinTron** introduces the **BreathTracker** series of digital Microlyzers



## Celiac

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the American Gastroenterological Association will look at papers like this, and will decide to adjust their guidelines and recommendations accordingly,” said Dr. Fasano, professor, Mucosal Biology Research Center, and Division of Pediatric Gastroenterology and Nutrition, University of Maryland School of Medicine, Baltimore. “Because everybody wins—the patients by not having to wait another 10 years to be diagnosed, the healthcare providers because they have the reward of resolving a puzzling clinical presentation, and the insurance companies because they will not have the patients utilize the network over and over again, but instead solve the problem.”

Peter H. Green, MD, professor of clinical medicine, and director, Celiac Disease Center, Columbia University College of Physicians and Surgeons, New York City, wrote an editorial in the *American Journal of Gastroenterology* that accompanied Dr. Fasano’s paper. He believes that the top priority should be for physicians—from primary care practitioners to internists—to consider celiac disease as a possible differential diagnosis in all patients with symptoms suggestive of celiac disease, such as weight loss, diarrhea and nutritional deficiencies.

“There should be more physician education, from medical school to fellowships, about the prevalence and wide range of clinical presentations of celiac disease,” Dr. Green told *Gastroenterology & Endoscopy News*. “And gastroenterologists also need to increase their own awareness of celiac disease and educate their referring doctors about its prevalence and diverse clinical manifestations, as well as about the availability and use of the various serological tests.”

Immunoglobulin (Ig) A deficiency is common in people with celiac disease, occurring at a rate of 1.7% to 3% compared with 0.05% to 0.1% in the general population. Therefore measurement of IgA levels is one of the necessary tests in patients suspected of having celiac disease. In his own practice, Dr. Green measures patients’ IgA serum levels, and also tests for the presence of IgA and IgG antibodies against tissue transglutaminase (tTG). The tTG IgA test has a sensitivity and specificity of >90%.

“These tests are easy to perform compared to the endomysial antibody [EMA] test, which requires an experienced technician to interpret the immunofluorescence results,” noted Dr. Green. “Thus I reserve the EMA test—which is traditionally considered the gold standard for celiac disease—for more difficult-to-diagnose cases.”

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—Peter H. Green, MD



Dr. Green then sends patients who appear likely to have celiac disease—even those with negative results on the serological tests, since the EMA and tTG tests produce false negatives in people who are IgA-deficient as well as in some individuals with normal IgA levels—for a duodenal biopsy. If there is still doubt remaining about the diagnosis after the biopsy, he orders tests for the presence of human leukocyte antigen (HLA) DQ2 or 8; these are 100% sensitive for celiac disease.

Dr. Fasano and his co-investigators followed a similar protocol, one that is recommended by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition in the most recent guidelines to address the diagnosis and treatment of celiac disease (Hill ID et al. *J Pediatr Gastroenterol Nutr* 2005;40:1-19). They recruited and studied 737 adult women and 239 adult men attending one of five participating university- or community-based internal medicine or family practice clinics in the United States and Canada between 2002 and 2004. Patients were recruited because they had symptoms suggestive of celiac disease and/or a family history of the disease, or had conditions putting them at elevated risk for celiac disease, such as an autoimmune disorder, Down’s syndrome, Turner’s syndrome, epilepsy or ataxia. The investigators interviewed a total of 2,568 people and found 1,709 to be eligible. Of these, 976 individuals were included in the study because 666 patients refused serological testing and 67 declined to complete the questionnaire.

The subjects’ median age was 54.3 years and 88.7% were white. The most common symptoms and/or conditions associated with celiac disease were bloating, chronic fatigue, irritable bowel syndrome, constipation and recurrent abdominal pain.

Thirty of the subjects (3%) had a positive IgA tTG test, and 18 women and four men were diagnosed with celiac

disease. Individuals with thyroid disease, a family history of celiac disease and gastrointestinal symptoms were the most likely to be diagnosed with celiac disease. Seventeen of the 22 diagnosed with the condition agreed to go on a strict gluten-free diet.

To determine the scale of the increase in diagnosis with thorough screening, the team also calculated the rate of diagnosis during the previous 12 months in the five practices. Only 15 patients had been diagnosed with the disease out of 54,988 who were seen at the participating practices, yielding a diagnostic rate of 0.27 cases per 1,000 physician visits. The diagnostic rate in Dr. Fasano’s study was 8.6 per 1,000 visits if the rate is based on the 2,568 subjects considered for inclusion in the study, or 11.6 per 1,000 visits if based on the 1,902 subjects who were eligible for the study but refused to undergo serological testing. These rates are 32 and 43 times, respectively, higher than in the previous year.

The investigators subsequently performed a cost-effectiveness analysis supported by a large healthcare insurance company, which has not been published. They found that the firm would save \$30 million per year by performing such screening, due to reduction in treatment of patients who otherwise would have remained undiagnosed until needing attention for complications.

“So screening the at-risk population is definitely cost-effective,” concluded Dr. Fasano. “It is also possible that screening the entire population is cost-effective, since this is an extremely frequent disease, affecting about 1% of the population, but that analysis remains to be done.”

The lead investigator of two celiac disease studies presented at the CDDW meeting agreed that screening is cost-effective as well as necessary, based on his results, and joined the call for more attention to the diagnosis of the disease.

“Celiac disease is very under-recognized by North American physicians,” said Decker Butzner, MD, professor,

Department of Pediatrics, Division of Gastroenterology, University of Calgary. “And on top of the problem of lack of proper testing, we’re still not screening many people with gastrointestinal and non-gastrointestinal symptoms that are suggestive of celiac disease, even though celiac disease is turning out to be one of the most common chronic diseases in North America.”

Dr. Butzner and two of his colleagues pored over the records of 9,533 people who had consecutive EMA testing through the Calgary Laboratory Services between March 2003 and July 2004, focusing on cases of inappropriate test interpretation. Only 49% (4,698/9,533) of these patients also had their serum IgA levels measured.

Moreover, the investigators uncovered 39 patients who had negative EMA test results but whose IgA test indicated a deficiency, rendering the EMA results unreliable. Only 49% (19/39) of those patients were given the appropriate next steps, which according to Calgary protocols are either IgG tTG testing or an intestinal biopsy. Among the 17 patients sent for biopsy, a diagnosis of celiac disease was confirmed in three cases. One of the patients with celiac disease also had chronic gastritis, and another had comorbid lymphocytic colitis.

“As many as nine additional cases of celiac disease likely went undiagnosed, due to physician errors in the evaluation and management of IgA-deficient patients undergoing celiac disease screening,” noted Dr. Butzner. “This represents an additional five percent of patients identified with celiac disease during the study period.”

In another poster presented at the CDDW meeting, Dr. Butzner and his co-investigators uncovered a 2% prevalence of celiac disease among patients being screened for celiac disease in Calgary. They also calculated the positive predictive value of the EMA test to be 91%, is sensitivity to be 95%, and that false positives occurred across the range of titers. Due to confusion surrounding appropriate screening, they have now implemented a system in which physicians simply check off a “celiac disease screening” box on laboratory requisitions. Well trained laboratory personnel then perform the appropriate tests, and supply interpretive commentary along with the results, advising physicians that patients with positive results should undergo a biopsy.

Dr. Fasano shares the belief that such a system could be useful elsewhere as a way of ensuring that more cases of celiac disease are detected, and hence reducing the considerable morbidity and mortality associated with the complications of the disease. ■