GASTRO-HEP News

By Kay Downer

ILLUMINATE Study Results Support Response-Guided Therapy with Telaprevir

In a new analysis of the ILLUMINATE study data, researchers found that a 24-week course of therapy with telaprevir (Incivek, Vertex), peginterferon α-2a, and ribavirin was noninferior to a 48-week course of telaprevir-based triple therapy among patients who had undetectable levels of hepatitis C virus (HCV) RNA at Weeks 4 and 12. This study by Sherman and colleagues enrolled 540 treatment-naïve patients, all of whom received triple therapy for the first 12 weeks: telaprevir (750 mg every 8 hours), peginterferon α-2a (180 µg per week), and ribavirin (1,000–1,200 mg per day). Telaprevir was discontinued after Week 12. After Week 20, patients who achieved extended rapid virologic response (defined as undetectable HCV RNA levels at Weeks 4 and 12) were randomized to continue peginterferon α-2a and ribavirin through either Week 24 or 48. All patients who did not achieve extended rapid virologic response continued treatment through Week 48.

Overall, 72% of patients achieved sustained virologic response (SVR), and 65% achieved extended rapid virologic response. Among patients who attained extended rapid virologic response, SVR rates were 92% in the group that received 24 weeks of treatment and 88% in the group that received 48 weeks of treatment (absolute difference, 4%; 95% confidence interval, –2% to 11%). This finding met the study's noninferiority criteria, which had established the noninferiority margin at 10.5%. In addition, there were fewer discontinuations due to adverse events in the group that received 24 weeks of therapy compared to the group that received 48 weeks of therapy (1% vs 12%; $P<.001$). Results of this study were published in the September issue of *The New England Journal of Medicine*.

Several Factors Predict Response to Proton Pump Inhibitor Therapy in Patients with Gastroesophageal Reflux Disease

Some patients with nonerosive reflux disease (NERD) and reflux esophagitis (RE) do not respond to standard doses of proton pump inhibitor (PPI) therapy. Furuta and associates in the Acid-Related Symptom Research Group therefore sought to identify factors that were associated with response to PPI therapy. Results of this study were published in the August 24th online issue of the *Journal of Gastroenterology*.

In this study, patients with symptomatic gastroesophageal reflux disease (GERD) received the PPI rabeprazole at a starting dose of 10 mg daily for 4 weeks. If heartburn was not relieved, the dose was increased to 10 mg twice daily for an additional 2 weeks and then to 20 mg twice daily for 2 more weeks. Complete heartburn relief was achieved in 42.5% of NERD patients and 67.9% of RE patients after 4 weeks; these rates increased to 68.9% and 91.7%, respectively, after dose escalation.

A multivariate analysis showed that several factors—such as female sex, frequent heartburn, and being a nonsmoker—were associated with resistance to the initial PPI therapy. Additional factors that were associated with PPI resistance included the following responses on the Frequency Scale for Symptoms of GERD (FSSG): a low score for question 4 (subconsciously rubbing the chest), a high score for question 3 (heavy stomach after a meal), or a high score for question 7 (unusual sensation in the throat). The authors concluded that the FSSG could help to predict whether patients with symptomatic GERD will respond to a PPI; they also noted that increasing the dose of rabeprazole is useful if patients are refractory to the standard dose.

Pilot Study Finds *Lactobacillus reuteri* Effective for Reducing Antibiotic-Associated Diarrhea

To determine whether administration of the probiotic *Lactobacillus reuteri* could help to prevent antibiotic-associated diarrhea in adults, Cimperman and coworkers conducted a randomized, double-blind, placebo-controlled pilot study. Results of this study were published in the October issue of the *Journal of Clinical Gastroenterology*.

Of the 31 enrolled patients, 8 patients were excluded from the analysis because they were enrolled in the study for less than 14 days; of the remaining patients, 13 patients received *L. reuteri* (1×10^8 colony-forming units twice daily) for 4 weeks, and 10 patients received placebo. Overall, this study found that patients who received the probiotic treatment had a significantly lower frequency of diarrhea compared to placebo-treated patients (7.7% vs 50%; $P=.02$). There were no differences between groups in terms of stool frequency or severity of gastrointestinal symptoms.