By Samantha Alleman

Sitafloxacin-Based Triple Therapy Developed to Treat *Helicobacter pylori*–Positive Patients

In a study published in the August issue of *Alimentary Pharmacology & Therapeutics*, Sugimoto and colleagues assessed the efficacy of sitafloxacin-based triple therapy and its relationship to antimicrobial susceptibility in *Helicobacter pylori*–positive Japanese patients. In this intention-to-treat analysis, 180 patients underwent a 1-week regimen of rabeprazole (10 mg 4 times daily), metronidazole (250 mg 2 times daily), and sitafloxacin (100 mg 2 times daily). Patients then underwent the 13C urea breath test at 8 weeks to measure their eradication status.

Of the 45 patients receiving first-line therapy, 100% (45/45; 95% CI, 83.4%-100%) achieved eradication. Thirty-eight of the 41 patients (92.7%; 95% CI, 80.1%-98.5%) receiving second-line therapy achieved eradication, while 83 of the 94 patients (88.3%; 95% CI, 80.0%-94.0%) receiving third-line therapy achieved eradication. Regardless of the number of prior attempts at treatment, no significant differences were found between the groups (P=.054). The overall eradication rate was 92.2% (166/180; 95% CI, 87.3%-95.7%).

In patients with sitafloxacin-sensitive and -resistant strains, eradication rates were 98.4% (60/61) and 50.0% (1/2; P<.001), respectively, while rates were 96.6% (28/29) in metronidazole-sensitive strains and 96.3% (77/80; P=.941) in metronidazole-resistant strains.

Adverse Events of Ledipasvir/Sofosbuvir With and Without Ribavirin in Patients With Hepatitis C Virus Infection

Alqahtani and colleagues conducted an analysis of data from phase 3 studies to evaluate the safety and tolerability of ledipasvir/sofosbuvir (LDV/SOF; Harvoni, Gilead) with and without ribavirin (RBV) in patients with chronic hepatitis C virus genotype 1 infection. Results of the analysis, which were published in the July issue of *Hepatology*, focused on treatment-related adverse events (AEs) and laboratory abnormalities based on data from 1952 patients.

In the study, 872 patients received LDV/SOF with RBV and 1080 patients received LDV/SOF alone. Patients in both groups underwent randomization to 8, 12, and 24 weeks of treatment. The patient population consisted of 440 treatment-experienced patients (23%), 224 patients (11%) with compensated cirrhosis, 308 patients (16%) who were African American, and 501 patients (26%) with a body mass index of at least 30 kg/m^2.

According to the researchers, treatment-related AEs (such as fatigue, insomnia, irritability, and rash/pruritus) developed in 71% and 45% of patients treated with and without RBV, respectively. Patients who were treated with LDV/SOF plus RBV were more likely to receive concomitant medications, need dose modification, or have their treatment interrupted due to AEs. In both groups, rates of serious AEs and resulting discontinuations were less than 1%. The sustained virologic response (SVR) rate was 97% for both treatments.

Mortality Rates of Medical Therapy Vs Elective Colectomy for Treatment of Ulcerative Colitis

As reported online on July 14, 2015 ahead of print publication in *Annals of Internal Medicine*, a retrospective matched cohort study was conducted to determine the mortality rates associated with elective colectomy vs medical therapy in patients with advanced ulcerative colitis (UC). Bewtra and colleagues applied Cox proportional hazard models to compare mortality rates between the 2 groups and to control for significant comorbidities using matched and adjusted analysis.

In the study, 830 patients underwent elective colectomy, and 7541 patients pursued medical treatment. According to the researchers, the mortality rate for elective colectomy was 34 deaths per 1000 person-years, whereas the mortality rate associated with medical treatment was 54 deaths per 1000 person-years (adjusted hazard ratio [HR], 0.67 [95% CI, 0.52-0.87]), although this result was not statistically significant in each sensitivity analysis. A post hoc analysis performed by age revealed improved survival with elective colectomy among patients 50 years or older who had advanced UC (HR, 0.60 [95% CI, 0.45-0.79]; P=.032 for age-by-treatment interaction).

Long-Term Biologic Therapy in Rheumatologic Patients With Previously Resolved Hepatitis B Viral Infection

Barone and colleagues evaluated the safety of various immunosuppressive biologic therapies in rheumatologic patients with previously resolved hepatitis B viral (prHBV) infection, the results of which were published in the July issue of *Hepatology*.

In the study, 1218 white rheumatologic patients taking biologic therapies who were outpatients between 2001 and 2012 were evaluated for liver aminotransferases in addition to anti–hepatitis C virus and HBV markers every 3 months. Beginning in 2009, patients who had prHBV infection and who were on immunosuppressive biologic therapy before and after 2009 underwent HBV DNA monitoring.

Of the patients studied, 179 were found to have prHBV infection (146 treated with anti–tumor necrosis factor- , 14 with rituximab, and 19 with other biologic therapies), and 959 patients were found to have no prHBV infection or other liver disease. The latter group was used as a control.

Patients with prHBV infection and rheumatologic indications for long-term biologic therapies did not have detectable HBV DNA serum levels or antibody to hepatitis B surface antigen/hepatitis B surface antigen seroreversion. The prevalence of increased aminotransferase levels in patients with prHBV infection was significantly higher compared with the control group, but only for aminotransferase levels greater than one times the upper limit of normal, and not for levels greater than two times the upper limit of normal. The data suggest that universal prophylaxis is not justified nor cost-effective in this setting.

In Brief

In a multicenter retrospective study, researchers found that a novel through-the-scope (TTS) balloon catheter system for small-bowel evaluation was safe and effective for deep enteroscopy. Compared with other forms of deep enteroscopy, the procedure time of the TTS balloon system was shorter, and diagnostic yield and depth of insertion were similar. No procedural adverse outcomes were noted. *Gastrointest Endosc*. 2015 Jun 16. Epub ahead of print. doi:10.1016/j.gie.2015.04.037.

Researchers conducting a multicenter, single-group, open-label, industry-sponsored study found that a single fixed-dose combination of LDV/SOF for 12 weeks provided high SVR rates in patients coinfected with HIV-1 and hepatitis C virus genotype 1 or 4. SVR12 rates were similar regardless of whether patients had received prior therapy or had cirrhosis. The most common AEs were headache, fatigue, and diarrhea; however, there were no treatment discontinuations because of AEs. *N Engl J Med*. 2015 Jul 21. Epub ahead of print. doi:10.1056/NEJMoa1501315.