

Boceprevir, Peginterferon Alfa-2b, and Ribavirin Triple Therapy for Patients With Genotype 1 Hepatitis C Infection

According to an August issue of *Lancet*, researchers conducted an open-label, multicenter, randomized, phase II, industry-funded trial (SPRINT-1) to evaluate the efficacy of the NS3 hepatitis C virus oral protease inhibitor boceprevir in combination with peginterferon alfa-2b and ribavirin. The first part of the trial consisted of 520 treatment-naïve patients with genotype 1 hepatitis C virus infection in 67 centers in the United States, Canada, and Europe. The patients underwent random assignment to 1 of the following arms: peginterferon alfa-2b 1.5 µg/kg plus ribavirin 800–1,400 mg daily for 48 weeks (PR48; n=104; the control group); peginterferon alfa-2b and ribavirin daily for 4 weeks, followed by peginterferon alfa-2b, ribavirin, and boceprevir 800 mg 3 times daily for 24 weeks (PR4/PRB24; n=103) or 44 weeks (PR4/PRB44; n=103); or peginterferon alfa-2b, ribavirin, and boceprevir 3 times daily for 28 weeks (PRB28; n=107) or 48 weeks (PRB48; n=103). In the second part of the trial, 75 patients underwent random assignment to either PRB48 (n=16) or low-dose ribavirin (400–1,000 mg) plus peginterferon alfa-2b and boceprevir 3 times daily for 48 weeks (low-dose PRB48; n=59). Higher rates of sustained virologic response were reported in all of the boceprevir arms than in the control arm (54%, 95% confidence interval [CI] 44–64, $P=.013$ for PRB28; 56%, 95% CI 44–66, $P=.005$ for PR4/PRB24; 67%, 95% CI 57–76, $P<.0001$ for PRB48; and 75%, 95% CI 65–83, $P<.0001$ for PR4/PRB44; vs 38%, 95% CI 28–48 for PR48 control). A high rate of viral breakthrough (27%) was associated with low-dose ribavirin, as was a rate of relapse (22%) similar to control (24%).

Predictors of Early Response to Infliximab in Patients With Ulcerative Colitis

The August issue of the *American Journal of Gastroenterology* included results of a large single-center cohort study assessing the efficacy and safety of the anti-tumor necrosis factor- α antibody infliximab for induction therapy in moderate-to-severe ulcerative colitis (UC). The study consisted of retrospective analysis of 90 UC patients who had received infliximab for 14 weeks. During the infliximab induction therapy, the colitis activity index and inflammation markers were noted. Researchers performed genotyping for UC-associated variants in the *IL23R* gene and in the *IL2/IL21* region. At week 2 (following the first infliximab infusion), 64.1% of patients receiving infliximab experienced clinical response to the drug, and 52.6% experienced remission. At week 14 (following

3 infusions), 61.0% experienced clinical response, and 52.5% experienced remission. The mean colitis activity index fell significantly from 10.4 points at week 0 to 5.1 points at week 2 ($P<.001$), to 4.4 points at week 6 ($P<.001$), and to 5.0 points at week 14 ($P<.001$). C-reactive protein levels and leukocyte counts ($P=.01$ and $P=.001$ at weeks 2 and 0, respectively) underwent significant reductions due to infliximab therapy. According to multivariate regression analysis, a high colitis activity index prior to infliximab therapy ($P=.01$) and negative antineutrophil cytoplasmic autoantibody status ($P=.01$) were independent positive predictors for response to infliximab. There was a greater likelihood of response to infliximab in homozygous carriers of inflammatory bowel disease (IBD) risk-increasing *IL23R* variants than in homozygous carriers of IBD risk-decreasing *IL23R* variants (74.1% vs 34.6%; $P=.001$).

New Distribution Agreement for *Helicobacter pylori* Breath Tests

The BreathID Breath Test System analyzes parts-per-million changes in carbon 13 and carbon 12 ratios in a patient's breath for the diagnosis of *Helicobacter pylori* infection. This breath test continuously measures breath, producing 10-minute results, and has demonstrated sensitivity and specificity for diagnosis. A multiyear US distribution agreement was recently announced between Exalenz Bioscience, Inc, and Sandhill Scientific, Inc, for this system, as well as for the Hp FasTest, which uses a dedicated BreathID device in the physician's office for immediate results, and the Hp BagTest, in which breath samples are collected and sent to a dedicated breath testing center for analysis.

In Brief

In a double-blind, placebo-controlled, multicenter trial, 2-week triple antibiotic therapy produced improvement, remission, and steroid withdrawal in active UC more effectively than a placebo. *Am J Gastroenterol.* 2010;105:1820-1829.

According to a meta-analysis of diagnostic accuracy studies, testing for fecal calprotectin is a useful screening tool for identifying patients most likely to require endoscopy for suspected IBD. The discriminative power to safely exclude IBD was significantly better in studies of adults than in studies of children. *BMJ.* 2010;341:c3369.