New research on improved treatment options and screening strategies for Hepatitis C

October 31 2011

Studies reporting on the effectiveness of new therapies for chronic Hepatitis C virus are among the clinical science presented at the American College of Gastroenterology's 76th Annual Scientific Meeting, where investigators also presented findings from an age-based risk assessment and screening intervention for Hepatitis C among Baby Boomers, patients aged 50-65, who saw a gastroenterologist for routine colon cancer screening.

With the recent introduction of new direct acting anti-viral therapies, physicians now have more options for treatment of chronic hepatitis, a chronic viral liver disease that infects more than 4 million Americans. Several studies of the new drug telaprevir in combination with the standard of care (pegylated interferon and ribavirin) looked at the drug's effectiveness among populations of patients who, because of race or failure of previous treatment, are considered hard-to-treat.

"Treatment Effect and Resistance Profiles were Similar Between Black/African American and Non-Black/African American Patients Treated with a Telaprevir Combination Regimen"

Dr. Andrew Muir of Duke University Medical Center and a group of investigators in a large multi-center trial evaluated data on safety and efficacy from two Phase 3 trials (ADVANCE and ILLUMINATE) of the direct acting anti-viral drug telaprevir in combination with the

standard of care (peylated interferon and ribavirin) for the treatment of chronic hepatitis C.

In African Americans, a group for whom the need for effective therapies is particularly urgent, a combination treatment of telaprevir with pegylated interferon and ribavirin provided a substantial improvement in "Sustained Viral Response" (SVR) – compared to the standard treatment. SVR means that the hepatitis C virus level is undetectable 6 months after stopping therapy and signifies the patient has been cured of the infection. Patients in the Black/African American group had an SVR rate of 61% when treated with the telaprevir combination compared to 25% with the previous standard of care.

"Response-guided Telaprevir Treatment in Genotype 1 Chronic Hepatitis C Patients who had Prior Relapse to Pegylated Interferon/Ribavirin"

Dr. Muir was also involved in an analysis of results of the Phase 2 (PROVE3) and Phase 3 (ADVANCE, ILLUMIATE and REALIZE) telaprevir studies of patients who relapsed to a prior treatment with the standard of care (pegylated interferon and ribavirin.) Prior relapsers are eligible for shortened duration with the telaprevir combination, and this analysis provides some of the rationale for the response-guided therapy approach for these patients.

The investigators looked at patients with prior relapse with peginterferon and ribavirin and then reported their response when given the telaprevir combination. The study reported SVR and relapse rates and studied the effect of the varying treatment durations in the different studies. They compared these results with the outcomes of those who had never been treated for Hepatitis C in the past.

The investigators also developed a viral dynamic model to predict SVR rates by different treatment durations of prior therapy with pegylated interferon and ribavirin, both in prior relapsers and treatment naïve patients. The observed clinical data supported the predictions of the model.

"Findings of this analysis suggest that among prior relapsers who had an early viral response and in whom the Hepatitis C virus was undetectable at 4 weeks and 12 weeks of therapy with a 24-week telaprevir combination treatment, their rates of sustained viral response were comparable to those in treatment-naïve patients, and relapse rates were low," explained Dr. Muir. Based on their findings, the investigators conclude that modeling predictions and the observed clinical data support the use of response-guided therapy in prior relapse patients.

Screening Baby Boomers for Hepatitis C during a Routine Colon Cancer Screening

Investigators at Scott & White Hospital in Temple, Texas developed and tested a screening intervention to identify those at high-risk for Hepatitis C virus among patients ages 50 to 65 who came to the hospital for a routine colonoscopy exam. This age cohort is an important target for Hepatitis C screening because research suggests that as much as 70 percent of the undiagnosed Hepatitis C infection in the United States is among Baby Boomers. At Scott & White, over one third of the 376 participants in the study had at least one risk factor for chronic Hepatitis C infection.

"Gastroenterologists are in the unique position of conducting colonoscopies and being experts on viral hepatitis," said Dawn Sears, M.D., the lead investigator. "We sought to assess the feasibility and acceptance of assessing risk factors and testing for viral hepatitis

infection during colonoscopy."

The three-month study recruited patients from among the 50 -65 age group undergoing routine colorectal cancer screening to complete questionnaires regarding vaccination, exposure, previous history of Hepatitis A or Hepatitis B or Hepatitis C. The patients were asked to disclose any risk factors including high risk sexual activity, injection drug use, tattoos placed before 2000, HIV status or hemophilia, among others.

The gastroenterology setting creates an opportunity to reach patients who, based on infection patterns in their age cohort, may carry chronic viral Hepatitis C infection but may be unaware of their status, because the recommendations for colorectal cancer screening begin at age 50.

Provided by American College of Gastroenterology