Hepatitis C in the News

April 27, 2015 By Lucinda K. Porter RN

There are two annual meetings that concentrate on liver disease, which includes hepatitis C infection. The fall meeting takes place in the U.S., and the spring meeting occurs in Europe. The European Association for the Study of the Liver (EASL) hosts the spring meeting, called the International Liver Congress (ILC). Technically the meeting is ILC, but everyone calls it EASL. This was the 50th ILC and today's blog offers some highlights.

Some good news for genotype 3 patients

In the U.S., genotype 3 patients have longer treatment lengths, the lowest success rates, and they still need to take ribavirin. Daclatasvir is under review in the U.S., and already approved in Europe, Japan and Brazil. A French study tested daclatasvir plus sofosbuvir in hepatitis C patients with genotype 3. Preliminary results (SVR24) showed high response rates in non-cirrhotics after 12 weeks of treatment. The response rate for cirrhotics was less impressive, but may be improved with 24 weeks of treatment or with the use of ribavirin.

Note: In 2014, Bristol-Myers Squibb (BMS) submitted a new drug application to the FDA for daclatasvir, but the FDA denied it. BMS resubmitted the application to the FDA on March 12, 2015. The application contains data to support approval for daclatasvir in combination with sofosbuvir (Sovaldi), and would be the first 12-week regimen specifically for the treatment of hepatitis C genotype 3. Results from a 12-week phase 3 clinical trial using daclatasvir and sofosbuvir (Sovaldi) in genotype 3 patients revealed SVR12 rates for treatment-naÃ¨ve of 90 percent; treatment-experienced had 86 percent SVR12 rates.

Also Note: Gilead's BOSON study using peginterferon, ribavirin, and sofosbuvir (Sovaldi) for 12 weeks had 93 percent SVR12 rates in genotype 3 subjects, compared to those receiving sofosbuvir plus ribavirin for 24 weeks (84 percent) or for 16 weeks (71 percent). Treatment-experienced genotype 3 patients with cirrhosis receiving sofosbuvir, peginterferon, and ribavirin had 86 percent SVR12 rates.

Exciting potential treatment for genotype 1 patients

In a small phase 2 study led by Edward Gane, Achillion's ACH-3102 and sofosbuvir in genotype 1 HCV patients yielded 100 percent SVR12 rates with 6 weeks of treatment. The combination was well tolerated.

Better treatment for genotype 5 patients

Genotype 5 is rare in the U.S., and represents only 1 percent of hepatitis C worldwide. It is the only genotype in which there is no alternative treatment for peginterferon. However, a 12-week study using ledipasvir/sofosbuvir (Harvoni) for 12 weeks yielded SVR12 results at 95 percent.

Delaying HCV treatment

A number of studies focused on the current practice of denying HCV treatment to patients who don't have at least stage 3 or 4 fibrosis. A Veterans Administration study found that delaying treatment until patients have advanced liver disease (cirrhosis) increases risk of morbidity and death.

Other EASL findings were:

- Cancer rates for all types of cancers is higher among patients with hepatitis C compared to those not infected. Hepatitis C is associated with non-Hodgkin's lymphoma, renal (kidneys) and prostate cancers, as well as liver cancer.
- Extrahepatic manifestations of hepatitis C may indicate an increased risk of cancer.
- Chronic hepatitis C infection is associated with a higher risk of developing cardiovascular diseases. Researchers in this study concluded that chronic HCV infection should be considered a risk factor for the development of cardiovascular diseases.

Hope for hepatitis C patients who fail the newest treatments

A phase 2 study conducted by Eric J. Lawitz and colleagues investigated ledipasvir/sofosbuvir (Harvoni) for 24 weeks in 41 genotype 1 HCV-infected patients who had failed previous therapies. SVR12 rates were 71 percent.

Another small but interesting presentation came from the NIH SYNERGY trial. HCV patients with stage 0 to 2 fibrosis who failed initial short course therapy with combination ledipasvir/sofosbuvir (Harvoni) with GS 9451 and/or GS 9669 were retreated for 12 weeks with ledipasvir/sofosbuvir (Harvoni). SVR12 data is not available, but SVR4 data is 94 to 100 percent. Assuming good final results, this might provide fuel for retreating hepatitis C patients who fail 8 weeks of Harvoni.

In the pipeline, the C-SALVAGE study enrolled 79 hepatitis C patients with genotype 1 who failed therapy with a direct-acting antiviral therapy (peginterferon and ribavirin plus either boceprevir, telaprevir, or simeprevir). Cirrhotic and non-cirrhotic patients were enrolled. They were given Merck's grazoprevir (MK-5172), elbasvir (MK-8742) and ribavirin for 12 weeks. SVR12 rates were 96 percent. Treatment was well tolerated with no drug-related serious adverse events. The most commonly reported adverse events were fatigue, headache, weakness, and gastrointestinal complaints.

Of Interest

Although still in early stages, keep an eye on hepatitis C treatment using Gilead's GS-9857 combined with sofosbuvir/GS-5816. Treatment-naÃ¨ve, genotype 1 patients without cirrhosis responded well with only six weeks of treatment.

A phase 3 trial found that Civacir effectively prevented HCV recurrence following liver transplants. Civacir was well tolerated with no drug-related serious adverse events.

Interesting reading, especially for Europeans is EASL's Recommendations on Treatment of Hepatitis C 2015.

Other Liver Diseases

Non-alcoholic fatty liver disease (NAFLD) dominated EASL. NAFLD is a serious problem in the U.S., and can create increased risk of liver disease, especially when coupled with hepatitis C. Research conducted by Nathan Johnson and colleagues found that exercise reduces liver fat. The type, intensity, and duration all had benefit. The message here is Research published in the April 2015 issue of *Hepatology* showed that intensity and duration do matter. Sechang Oh and colleagues recruited 169 obese middle-age men in Japan and found that the biggest improvements occurred with > 250 minutes per week of moderate to vigorous exercise.

What's Missing

Research regarding treatment for children with hepatitis C. Until we have treatment for all patients, hepatitis C remains in the dark ages.

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