Hepatitis C Highlights of the 2015 Liver Meeting

November 23, 2015 By Lucinda K. Porter RN

Selecting my favorite hepatitis C research presented at the recent annual meeting of the American Association for the Study of Liver Diseases (AASLD) is like picking a favorite star in the sky. There are so many to choose from and they were all beautiful. Here are the ones that dazzled me.
I will begin with three studies presented at AASLD that were also published in the *New England Journal of Medicine* (NEJM), all using Gilead's sofosbuvir/velpatasvir.

Article: *Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection* - J.J. Feld, et al. NEJM November 16, 2015
Gist of the Study: This phase 3 study enrolled 624 untreated and previously treated subjects with chronic hep C genotype (GT) 1, 2, 4, 5, or 6 infection, including those with compensated cirrhosis. All received either placebo or a sofosbuvir/velpatasvir tablet once daily for 12 weeks. (GT 5 participants did not receive placebo.)

Bottom Line: Overall sustain virologic response rate (SVR) was 99 percent.

- GT1a: 98%
- GT1b: 99%
- GT2: 100%
- GT4: 100%
- GT5: 97%
- GT6: 100%

Discussion: Adverse events in the placebo versus sofosbuvir/velpatasvir groups were very similar. Less than 1 percent of the subjects in the sofosbuvir/velpatasvir group had lab abnormalities. Only one participant dropped out of the study early because of an adverse event. She reported an anxiety attack on day 13 of the study. Of the 15 serious adverse events, none occurred in more than one subject. One subject died in his sleep on day 8, and the cause of death has not been determined.
Comments: Amazing, but what about GT3? Read on...
Article: *Sofosbuvir and Velpatasvir for HCV Genotype 2 and 3 Infection* - G.R. Foster, et al. NEJM November 16, 2015
Gist of the Study: Two phase 3 studies of untreated and previously treated subjects with chronic hep C

GT 2 or 3 infection, including those with compensated cirrhosis. In one trial, hep C GT 2 subjects received a single sofosbuvir/velpatasvir (SOF/VEL) combo tablet (134 subjects) or sofosbuvir plus ribavirin (SOF/RBV 132 subjects) once daily for 12 weeks. In the other trial, hep C GT 3 subjects received either a single SOF/VEL combo tablet (277 subjects) or SOF/RBV (275 subjects) once daily for 12 weeks.

Bottom Line: In the GT 2 study, the SVR rate in SOF/VEL group was 99 percent; SOF/RBV was 94 percent. In the GT 3 study, the SVR rate in SOF/VEL group was 95 percent; SOF/RBV was 80 percent.
Discussion: The most common adverse events in the two studies were fatigue, headache, nausea, and insomnia. In the two studies, one participant dropped out early because of an adverse event. He reported anxiety, headache, and difficulty concentrating on the first of the study.
In the GT 2 study, two subjects had serious adverse events in each arm. In the GT 3 study, the SOF/VEL arm had fewer serious adverse events (2 subjects) compared to the longer SOF/RBV arm (5 subjects).
Two subjects died in the post-treatment follow-up in the GT 2 study SOF/VEL arm; one from complications from metastatic lung cancer nearly four months after treatment; the other from cardiac arrest more than four months post-treatment.
In the GT 3 study, three deaths occurred in the SOF/RBV arm. During the study, one died from an unknown cause, the other from a gunshot wound. In the post-treatment phase, a third died from an unknown cause.
Comments: Fabulous results for GT 3 patients. The death from a gunshot wound in the ribavirin arm was distressing given how many of us have taken ribavirin. Glad I didn't have access to a gun when I was on treatment.
Article: *Sofosbuvir and Velpatasvir for HCV in Patients with Decompensated Cirrhosis* - M.P. Curry, et al. NEJM November 16, 2015
Gist of the Study: This a phase 3 trial enrolled 267 previously untreated and treated subjects with HCV genotypes 1 through 6 who had decompensated cirrhosis (Child-Pugh-Turcotte class B). They received either sofosbuvir/velpatasvir (SOF/VEL) once daily for 12 weeks, SOF/VEL plus ribavirin (RBV) for 12 weeks, or SOF/VEL for 24 weeks.
Bottom Line: Overall SVR rates were 83 percent in the SOF/VEL 12 week group; 94 percent in the SOF/VEL plus RBV 12 week group; 86 percent in the SOF/VEL 24 week group
Discussion: Serious adverse events ranged from 16 to 19 percent. There were nine deaths, most due to complications of end-stage liver disease. The most common adverse events were fatigue, nausea, and headache. Subjects who were taking ribavirin also had anemia.
Comments: The ribavirin-free arms of this study look quite promising in this most difficult to treat group.
Abstract #1785 *Application of a Novel Hepatitis C Virus Antigens Enzyme Immunoassay (HCV-Ags EIA) for One-step Diagnosis of Active HCV Infection Using Urine Specimens* - Ke-Qin Hu and Wei Cui **The Bottom Line:** Using HCV antigen testing, this small study was able to screen and diagnosis HCV infection in a single step with a urine sample. If this works, then we could skip the two-step process we currently use of testing for antibodies and the viral load. Plus it's noninvasive!
Abstract # 313 *The Need for Improved Liver Literacy in the US Population* - Tracy J. Mayne and Herbert Swanson **The Bottom Line**: Researcher learned that the public knows very little about liver health. This one fact tells it all: nearly half of those surveyed believed that a person can live without a liver.
Abstract # 152 *Treating Hepatitis C in the US: measuring impact and value in the context of other major health interventions* - Mai T. Pho1, et al. The Bottom Line: This analysis found that even at the current costs, the net benefit of treating hepatitis C is great.
Other noteworthy AASLD presentations posted on Hep's website:

- Hepatitis C May Transmit Sexually From Rectum without Blood
- High Genotype 2 and 3 Hep C Cure Rates for New AbbVie Combo
- Near-Perfect Results for New AbbVie Hep C Combo in Genotype 1s
- Daklinza and Sovaldi Cure High Rates of Hard-to-Treat Hep C
- Daklinza & Sovaldi Better Treats Those with HIV & HCV
- Fast Responders May Only Need 3 Weeks of Triple Hep C Therapy
- High Hep C Cure Rates for 8-Week Merck Triple Therapy

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