Hep C Dispatches From Major Conference on Viruses

March 13, 2015 By Benjamin Ryan

The annual Conference on Retroviruses and Opportunistic Infections (CROI) is typically dominated by HIV research. In recent years, however, hepatitis C virus (HCV) has taken a major place at the table as well, as research into treatment of the virus advances at a breakneck pace. To follow are summaries of the findings of notable hep C studies that were presented at this year's conference, which took place in Seattle from February 23 to 26. For more details on each study, click the subheadings.

High Rates of Advanced Liver Damage in Hep C–Diagnosed Boomers

Combing Quest Diagnostics' data from 2010 to 2013, researchers found that baby boomers diagnosed with hep C have high rates of advanced liver fibrosis and cirrhosis.

Out of the nearly 273,000 people diagnosed with hep C during this period, about 125,000 were included in the analysis because there was enough data on them to determine their age and estimate the severity of their liver damage. Of this group, 87,000, or 68 percent, were born between 1945 and 1965, making them baby boomers.

Among all age groups, 20 percent had little or no fibrosis, 35 percent had mild-to-moderate fibrosis, 22 percent had severe fibrosis, and 18 percent had cirrhosis. For the baby boomers, these figures were a respective 9 percent, 39 percent, 26 percent and 21 percent.

New Hep C Treatments Are Cheaper Per Cure

Treating hep C with the hugely expensive combination of Sovaldi (sofosbuvir) and Olysio (simeprevir) is still cheaper per cure than treating with the far less effective interferon and ribavirin. Researchers looked at data from 173 people treated with Sovaldi and Olysio, with or without ribavirin, in New York City. Out of this group, 153, or 88 percent, were cured.

The researchers calculated that the total price to treat all 173 participants, including the cost of medications, lab testing, any treatment for side effects, and clinic fees, was $26 million, or about $150,000 per person. Considering that 20 people did not achieve a cure, the cost per cure was

about $171,000. This is below the $189,000 cost per cure for interferon and ribavirin treatment found in previous research.

The cost per cure with the newer treatments could be considerably lower if an insurer were to secure discounts. Harvoni treatment, for example, costs $94,500 for a 12-week treatment, or $63,000 for those who only require eight weeks, and many insurers have negotiated cut rates with Gilead Sciences, which manufactures the treatment. On the other hand, there is a much greater demand for cures now, meaning that the overall costs to insurers for hep C treatment is still sky-high.

High Risk in Delaying Hep C Treatment for HIV/HCV Coinfected People

If people coinfected with HIV wait for liver damage to progress before starting hep C treatment, they are essentially playing Russian roulette with liver-related complications and death.

Liver scarring, known as fibrosis, is "staged" using the five-level Metavir scoring system. F0 means there is no fibrosis, F1 through F3 is fibrosis of increasing severity, and F4 is cirrhosis.

Researchers used computer modeling and data from the Swiss HIV Cohort Study to make their projections. They estimated that, when compared with treating all coinfected people immediately after a hep C diagnosis, delaying treatment until one year after diagnosis or until individuals reach Metavir stages F2, F3 or F4, led to a respective 14, 43, 142 and 418 additional cases of liver-related deaths per 1,000 people.

The estimated likelihood that people will experience decompensated cirrhosis, liver cancer, or liver-related death increases steadily as treatment is delayed, with especially high rates of these consequences if treatment is delayed until someone reaches F3 or F4. When waiting to treat until an individual reaches F3 or F4, the approximate estimated likelihood of decompensated cirrhosis is about 35 percent or 60 percent, respectively; the respective likelihood of their developing liver cancer is about 10 percent or 30 percent; and the respective likelihood of dying of liver-related causes is about 19 percent or 53 percent.

Olysio Clashes With Certain HIV Meds

People coinfected with HIV and hep C who are looking to undergo HCV treatment with Olysio (simeprevir) may need to change HIV medications to avoid drug-drug interactions. Researchers examined data on 133 coinfected patients in the University of Pittsburgh Medical Center's HIV/AIDS program, covering the period of June to October 2014.

Eighty-six percent of this group had genotype 1 of hep C, and 94 percent of the overall group was taking antiretroviral (ARV) therapy for HIV. Thirty-eight percent of those taking ARVs were on a Norvir (ritonavir)–boosted protease inhibitor regimen; 34 percent were taking Sustiva (efavirenz), 11 percent took Isentress (raltegravir), 6 percent Edurant (rilpivirine), 1 percent elvitegravir/cobicistat, and 4 percent took other ARVs, such as Tivicay (dolutegravir).

A total of 103, or 77 percent, of the of the individuals had to switch ARVs before beginning Olysio treatment. Forty-seven, or 46 percent, of them were able to make a straightforward substitution. Forty, or 39 percent, needed to consult with an HIV clinician before switching ARVs. Sixteen people, or 15 percent, were not able to switch because of resistance to certain ARVs. More than 30 percent of those taking a protease inhibitor couldn't make a switch.

96% Hep C Cure Rate for Harvoni in Those Coinfected With HIV

Gilead Sciences' Harvoni (ledipasvir/sofosbuvir) cured almost all people with genotype 1 of hep C, as well as a small number of those with genotype 4, all of whom were coinfected with HIV. The Phase III study of 12 weeks of Harvoni included 335 coinfected participants; 98 percent had genotype 1, and 2 percent had genotype 4. Fifty-five percent of the participants had failed a previous hep C therapy.

All of the participants had a fully suppressed HIV viral load thanks to antiretroviral (ARV) therapy, and were taking one of three regimens: Atripla (efavirenz/tenofovir/emtricitabine), Truvada (tenofovir/emtricitabine) and Isentress (raltegravir), or Complera (rilpivirine/tenofovir/emtricitabine).

A total of 321 out of 335, or 96 percent, participants were cured. Gilead intends to file a supplemental new drug application with the U.S. Food and Drug Administration (FDA) to include these results in the Harvoni label.

Daclatasvir and Sovaldi Cure 97% of Hep C in Those Coinfected With HIV

Bristol-Myers Squibb's (BMS) daclatasvir and Gilead Sciences' Sovaldi (sofosbuvir) cured 97 percent of those with genotypes 1 through 4 of hep C who were coinfected with HIV. The Phase III trial took 151 participants who had never been treated before and randomized them so that for every two people who were assigned to receive 12 weeks of treatment, one person was assigned to eight weeks. Another 52 participants who had failed a previous treatment took daclatasvir and Sovaldi for 12 weeks. The participants included those with compensated cirrhosis.Seventy-six percent of the participants had HCV genotype 1, while 24 percent had genotypes 2, 3 or 4.

The daclatasvir dose was 60 milligrams, once a day, but this could be adjusted to 30 mg or 90 mg, depending on the individual's HIV treatment regimen. Everyone took 400 mg of Sovaldi, once daily.

Ninety-seven percent (149) of the 153 people treated for 12 weeks were cured. Just 76 percent (38 of 50) of those who were treated for eight weeks achieved a cure.No one stopped taking treatment because of side effects, and none serious side effects reported were deemed related to the hep C treatment.

Two weeks after the conference, BMS filed an amended new drug application with the U.S. Food and Drug Administration (FDA) for approval of a 12-week regimen of daclatasvir and Sovaldi to

treat people with genotype 3 of hep C. A decision is expected by mid-September.

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