HCV Drugs

This article discusses the recently released data from Achillion, touching on various issues related to current treatment, such as drug-drug interactions, medical providers and insurance companies, and those who are still the most difficult to treat; it originally appeared in the HCV Advocate

November 4, 2015 By Alan Franciscus

Achillion

On September 17, 2015, Achillion announced the second part of their Phase 2 study (the PROXY study) of odalasvir (ACH-3102) and sofosbuvir to treat genotype 1. The cure rates were 100% (6 of 6 patients). Earlier, Achillion had announced a 100% cure rate for 12 patients treated for eight weeks, and a 100% cure rate for 12 patients treated for six weeks. Although there was a small number of patients in the PROXY study, this is encouraging data.

The study used Gilead's drug—sofosbuvir—as the proxy drug. A proxy drug is used as a placeholder while another drug is being developed and tested by a pharmaceutical company—in this case Achillion. Also noteworthy, Achillion and Janssen are collaborating to develop and commercialize HCV drugs worldwide. Janssen has many drugs in development to treat hepatitis C. As well, Gilead, AbbVie, and Merck have drugs in the pipeline. Merck's new combination of two drugs is expected to be approved by the Food and Drug Administration (FDA) in early 2017.

Medical Providers

Patients are not the only ones who are having a difficult time with the insurance restrictions. Medical providers who have to tell their patients are also upset. Many providers have to spend a lot of time submitting paperwork over and over trying to get their patients' medications approved. It takes up an inordinate amount of the medical provider and office staff's time—many times only to be told that the insurance claim was denied. As you can imagine it breaks their hearts to tell a patient "there is a cure, but I cannot give you it because insurance will not cover it."

Insurance

There are other issues that are difficult for patients,medical and service providers. Access to the new medications can be very difficult depending on your insurance carrier. Many people are being denied access to these life-saving HCV medications unless they have more serious disease progression. Shame on the insurance companies that are not covering HCV medications! It doesn't help that the price of the drugs are so expensive.

The Current State of HCV Therapy

We have certainly come a long way compared to the interferon days. Additionally, many populations—HIV/HCV coinfection, Latinos, compensated cirrhosis,healthy liver-transplanted—and other groups had very low cure rates.

The current state of HCV treatment is nothing short of amazing. Current therapy cures up to 90% to100% of people with HCV genotype 1, 2, and 4. The medications also have lower side effects and shorter treatment duration.

The improvements in cure rates are impressive especially in certain populations with hepatitis C. In the September 2015 "Mid-Month Edition" of the HCV Advocate newsletter I wrote about 3 different clinical trials using 3 different combinations of direct-acting antivirals to treat HCV in people coinfected with HIV. The patient populations in these studies included many of the patient characteristics previously considered the most difficult to treat—people with HIV, genotype 1a, cirrhosis, Black patients, previously treated patients—all who had not achieved a cure. The cure rate in the three trials ranged from 96% to 98%. Another population that has had dramatic improvements is liver transplanted patients (with moderate liver function and compensated cirrhosis). The cure rates were 96% - 98%.

Drug-Drug Interactions

A very important issue with the new direct antiviral medications is the potential for drug-drug interactions (DDIs). This is more of an issue for people of the Baby Boomer generation who may take additional medications for blood pressure, diabetes, cholesterol, etc.People who are infected with HIV/HCV are also at risk for DDIs. There is also a risk of DDIs with common over-the-counter medications and herbs. This is why it is so important to tell your medical provider(s) about anything you are taking.

Still Difficult to Treat

A caveat: Even though we need better therapies and strategies to treat the most difficult to treat patients listed here, the DAA therapies are still vast improvements from the older therapies in the people and groups below.

People with genotype 3 with cirrhosis and who have not been cured with a previous course of treatment are an unmet medical need. Current treatments only yield cure rates in the 60 percentile. There is an option of adding pegylated interferon. I wrote about this before and advised people to think about this but I did not get a very positive reaction.

People with decompensated cirrhosis are at risk for severe disease progression, but unfortunately, current treatment does not work as well. Similarly, people with end-stage kidney disease or people who are on dialysis also have a large unmet medical need. Note: Merck's new combination looks very promising for this group of patients. People who do not respond to a previous course of therapy are another difficult group to treat,but treatment strategies are slowly evolving.

Re-Treatment

For someone who has relapsed, coming up with a plan to prescribe the right combination of drugs

to optimize the chances of re-treatment success is more difficult with the development of RAVs (see a brief overview of RAVs in this issue).

There have been many advances in hepatitis C treatment in a short period of time. Hopefully, many of the treatment issues listed above will be quickly resolved.In the meantime, we all have to advocate for ourselves and others with hepatitis C and remember to thank those medical providers who are providing such wonderful care.

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