Coinfected With HIV and Hep C? Time To Party Like It’s 1996

As hepatitis C treatment undergoes a revolution akin to the introduction of HIV antiretrovirals, the doors are swinging wide open for people coinfected with HIV to be cured of hep C.

March 18, 2014 By Benjamin Ryan

If you think that having HIV means you can't be cured of a coinfection with hepatitis C, then think again. If you think the only way to rid yourself of the hepatitis C virus (HCV) and to spare your liver of its damaging consequences is to undergo a year of interferon treatment, suffering from the drug's miserable flu-like side effects, there is good news for you.

The hep C revolution is upon us. Echoing the 1996 introduction of HIV antiretroviral cocktails, 2014 is all but certain to go down in history as HCV's watershed year (give or take a few months on either end). Two highly tolerable new drugs, Gilead Sciences' Sovaldi (sofosbuvir) and Janssen's Olysio (simeprevir), were approved at the close of 2013, expanding current treatment options and upping the chances of a cure for both mono- and coinfected people with hep C. ("Coinfected" is shorthand for having both HIV and HCV.) More important, though, these drugs have set the stage for the likely introduction, beginning later this year or early next, of numerous combination hep C treatments that will do away with interferon for good and up cure rates to near-perfect levels.

As recently as three years ago, hep C was very difficult to treat, requiring the dreaded year of interferon, plus the drug ribavirin, which can cause anemia. The chance of actually curing the virus was low enough to call into question whether such onerous treatment was actually worth the price in personal suffering. The prospects were especially bleak for those coinfected with HIV—studies put cure rates as low as 27 percent—because HIV blunted interferon's therapeutic effects. Cirrhosis, which is more common in those who are coinfected, also took a bite out of interferon's efficacy.

The 2011 introduction of two hep C protease inhibitors, Incivek (telaprevir) and Victrelis (boceprevir), improved cure rates and often cut treatment time in half, but still required interferon and ribavirin.

When the U.S. Food and Drug Administration approved Sovaldi in December 2013, many in the hep C clinical community were stunned by, not to mentioned thrilled over, the FDA's declaration that having HIV placed no additional restrictions on the chances for treatment with the drug. No

previous hep C therapy had even been specifically approved by the FDA for use among people coinfected with HIV. In fact, numerous research studies on Sovaldi and on promising drugs in the hep C pipeline have found that cure rates no longer differ between mono- and coinfected people who undergo these cutting-edge therapies.

“We started almost 200 [people] on treatment in December,” says Douglas Dieterich, MD, a professor of medicine at Mount Sinai Hospital in New York City, of the both mono- and coinfected patients in his practice’s care. “We’re seeing the follow-ups now at week eight [of treatment]. Nobody has any side effects. We keep waiting for the other shoe to drop, and nothing’s happening. They all feel great.”

Daniel Fierer, MD, is an assistant professor of medicine in infectious diseases, also at Mount Sinai, who treats a significant coinfected population. He has found that many coinfected people have been so alienated by the historically dispiriting news about their chances for obtaining a hep C cure that they have essentially tuned out and dropped out of HCV care. Re-engaging this demographic is particularly critical not only because of how rapidly treatment options are improving, but also because HIV accelerates the progression of liver disease in people with HCV, meaning that those who are coinfected tend to suffer greater liver damage.

“This is the time to get back into [hep C] care, get back into thinking about it,” Fierer says. “Bug your doctor about it now. Now.”

According to Fierer, it is vital that all of those living with both HIV and HCV see a liver specialist or a gastroenterologist who specializes in hepatitis C who can “stage” their liver disease—establishing the level of damage to the organ. Those who have the most advanced stage, cirrhosis, have the most urgent need of treatment, especially considering that liver disease is the leading cause of death among the coinfected population.

Which begs the question: Should you treat hep C immediately, or wait for newer drugs to hit the market, likely in the next nine to 12 months? For coinfected people, the biggest drugs in the pipeline to watch are Gilead’s ledipasvir and Bristol-Myers Squibb’s daclatasvir. If approved, either one of them may be used in an interferon-free combination with Sovaldi, likely allowing for 95 percent-plus cure rates after as little as six to 12 weeks of treatment. Plus, the probability of drug-drug interactions between these drugs and HIV medications should be slim.

“Almost bulletproof,” is how Fierer puts such treatment prospects.

Currently, Sovaldi, along with ribavirin and in some cases interferon as well, is the primary hep C treatment option for people coinfected with HIV and HCV. Cure rates for most people are in the 85 to 95 percent range. Treatment lasts for 12 to 24 weeks, depending on which genotype of hep C you have. The drug is only approved for genotypes 1 through 4, but physicians may prescribe it “off label” to those with other genotypes. Genotype 1 is the most common in the United States.

As for getting interferon off the ticket, those who have genotypes 2 and 3 can avoid the drug

under current FDA guidelines, undergoing treatment with just Sovaldi and ribavirin. Interferon is still required for the other genotypes until new drugs emerge from the pipeline. However, for those with genotype 1, the FDA has given clinicians the option of considering interferon-free treatment to those who are “ineligible” to take the drug. Some clinicians have argued that the simple desire not to want to take interferon qualifies as an ineligibility.

Avoiding interferon when treating genotype 1 of hep C with Sovaldi requires a trade-off, however, both in terms of treatment length and in the chance of a cure. A combination of Sovaldi, interferon and ribavirin requires just 12 weeks of treatment and has a cure rate of 89 percent overall, including 80 percent for those with cirrhosis and 92 percent for those without. Without interferon, treatment time must increase to 24 weeks and overall cure rates drop to 76 percent.

Sovaldi is an especially good choice for people with HIV because the drug has been studied with many HIV medications and has shown no serious drug-drug interactions, except with ritonavir-boosted Aptivus (tipranavir). Just as with HIV meds, hepatitis C drugs have various classes, each of which attacks the virus at different points in its life cycle. Because there are hep C protease inhibitors (PIs) just as with HIV, the overlap when both are taken at one time can cause a problem because the drugs are metabolized through the same pathway in the liver. The amount of each drug that winds up in the blood can raise or lower as a consequence, sometimes to dangerous levels. The second currently available hep C medication on the market, Olysio, is an NS3/4A protease inhibitor. Consequently, there are reduced options when pairing Olysio with HIV medications.

Meanwhile, a handful of pharmaceutical companies are racing to complete development of new therapies to add to the mix. According to Jean-Michel Pawlotsky, MD, PhD, of Henri Mondor University Hospital in Créteil, France, “The studies with HIV-coinfected patients are a little bit late compared with monoinfected patients.” Nevertheless, he thinks clinicians will be able to pull together enough information from various studies to guide them in effectively and safely treating coinfected patients when new drugs arrive on the market.

Such challenges should prove relatively surmountable, especially when compared with the difficulties that have long faced those seeking a cure for hepatitis C. Fierer, for one, advocates spreading the word far and wide that the future is upon us.

“Those of us who know more don’t always recognize how stuck and hopeless a lot of people feel,” he says. “We need to find those people and tell them it’s no longer hopeless. We have a new era, and it really works, and we’re not kidding. It’s not like, ‘Oh, what’s the catch?’ There isn’t a catch right now.”

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