Should We Keep Pushing for Shorter Hep C Treatments?

One research team has broken down the risk and benefits associated with treating more people in eight weeks or fewer.

September 22, 2017 By Benjamin Ryan

Treatment options for people with hepatitis C virus (HCV) keep expanding by the year, better meeting the needs of numerous subgroups, such as those with chronic kidney disease or cirrhosis. Twelve weeks of thearpy with direct-acting antivirals (DAA) typically has a greater than 90 percent success rate at vanquishing the virus. Some people with harder-to-treat cases need to take 24 weeks of therapy to raise their chances of a cure, while a significant proportion of the hep C population can beat the virus with just eight weeks with some regimens, including Gilead Sciences' Harvoni (ledipasvir/sofosbuvir) and AbbVie's newly approved Mavyret (glecaprevir/pibrentasvir) .

As recently as the last decade, when interferon was the cornerstone of hep C therapy, curing the virus was something of a nightmare, requiring as long as a year of onerous treatment involving flu-like side effects, with a poor chance of success.

Considering these factors, at this point in the modern era of DAA treatment one might expect hep C researchers to rest on their laurels.

"It would be easy enough for us to be like, 'OK, we have a cure that works for 95 percent of people—all you need is 12 weeks,"' says Eleanor M. Wilson, MHS, MD, an assistant professor of medicine at the Institute of Human Virology at the University of Maryland School of Medicine in Baltimore. Instead, she advocates a more restless stance on improving outcomes for the hep C population as a whole, saying, "So let's see how much we can push the envelope and really try to get more people treated and reduce the burden overall. It's exciting."

Wilson and others in the hep C research community are keen to find ways to allow a greater proportion of the hep C population a chance for a cure in eight weeks or fewer with available or forthcoming treatments. (Meanwhile, the mad dash for huge profits motivates the pharmaceutical industry to develop therapies that allow for ever-shorter treatment lengths so as to best the competition's regimens.)

Wilson is a coauthor on a recent paper published in The Lancet Gastroenterology & Hepatology that took a close look at the overall drive to reduce hep C treatment time. As she and her

colleagues write in their paper, this mission introduces an ethical balancing act guided by numerous moving parts.

A main factor is money. Despite a recent decline in the average cost of treatment thanks to increased competition among pharma companies, DAAs remain astronomically expensive, not to mention highly in demand. Consequently, insurers, including Medicaid, have been limiting who can receive coverage for the medications.

Because pharmaceutical companies charge the U.S. health care market by the pill instead of a fixed price per overall hep C treatment, there is a considerable financial incentive to treat for shorter periods. And presumably, if a greater proportion of the hep C population spent less time on treatment, this would free up resources to treat more people.

Then there's the matter of the U.S. health care system's capacity to treat the glut of people with hep C who are waiting for a chance at a life free from the virus. An estimated 2.7 million U.S. residents have hep C, and a bit less than half of them have been diagnosed. Yet there are only 20,000 specialists working in the fields of hepatology, gastroenterology and infectious disease across the country. And insurers tend to favor these specialists when granting prior authorization to prescribe DAAs, which complicates matters for those who advocate training nonspecialists, including internists and even nurse practitioners, to treat hep C.

Given these limitations, reducing the average amount of time medical providers spend monitoring individuals undergoing hep C treatment would likely allow them to squeeze in more patients.

Additionally, while considerable research supports the overall finding that today's crop of DAAs are generally safe and well tolerated, there are always risks involved with taking medications. So, according to Wilson, to mitigate such potential harms, it's probably best to favor a shorter period of treatment.

The major flip side to all these potential benefits of shorter treatment is that in some cases, treating for less time may raise the risk that the therapy will fail. Not only may a higher rate of individuals experience a return of the virus following treatment, known as a viral relapse, but more people could see their virus develop resistance mutations that may compromise future treatment options.

Such negative outcomes may be disappointing and burdensome to the individual, especially when he or she must face another round of treatment and ultimately stay on therapy for much longer than otherwise would have been necessary had they not attempted the shorter treatment in the first place. But research suggests that on a population level, this strategy will still save time and money, succeeding in drawing down the average number of weeks individuals spend on treatment.

Wilson says that retreatment cure rates among those who are not cured by a course of DAAs these days tend to be reassuringly high. For example, in the SYNERGY trial, those who were not cured after taking Harvoni plus one or two additional DAAs for only four to six weeks had a 91 percent

cure rate after receiving a second go-round, this time with 12 weeks of Harvoni.

“Now,” Wilson says, “with so many retreatment options, I think there’s still reason not to be daring, exactly, but to give more people a shot with shorter first therapy because they have a recourse. And that way you might be able to expand initial therapy to so many more people.”

Research has suggested that the current guidelines recommending 12 weeks of treatment for certain groups may result in excessive time on therapy in some cases. In one trial of AbbVie’s Viekira regimen (ombitasvir/paritaprevir/ritonavir; dasabuvir), treating for only eight weeks instead of the standard 12 or 24 weeks resulted in a robust 98 percent cure rate among 166 individuals. In the POLARIS-2 trial, eight weeks of Gilead’s newly approved Vosevi (sofosbuvir/velpatasvir/voxilaprevir) cured 95 percent of 501 individuals with genotypes 1 through 6, including both those with and without cirrhosis and those who had not been treated before.

Keeping the hep C treatment length at eight weeks or fewer may also improve individuals’ adherence to their daily DAA drug regimen. Research indicates that adherence is higher during the first four to eight weeks of hep C treatment and then tends to drop off.

However, the degree to which adherence to DAA regimens factors into the likelihood of a cure remains rather foggy. Wilson reports anecdotal evidence of nonadherent hep C patients who took only a few weeks of treatment when they were supposed to take many more and still beat the virus. But such cases are rare, and the prevailing wisdom remains that it’s very important for people to take their hep C medications daily and for the length prescribed.

In the future, identifying who is more likely to succeed on treatment running for fewer than eight weeks may in some scenarios require more careful pretreatment screening. For example, in the SYNERGY trail, researchers found that participants were more likely to achieve a cure from sub-eight-week treatment regimens if before starting therapy, they had a lower hep C viral load, were younger, had genotype 1b and lower level of risky viral resistance mutations.

The authors of one recent paper found that testing the viral load during the first or second week of treatment could provide clues that would help predict the necessary length of therapy.

Another, quite small study including 18 people with genotype 1b and no cirrhosis found that those treated with a triple-DAA regimen whose viral load dropped particularly rapidly by the second day of treatment (to below 500) may need to stay on therapy for only three weeks.

Such so-called response-guided treatment was a major component of hep C therapy during the interferon era. Reintroducing such a method and asking clinicians to engage in more complex decision making before settling on a prescription could deter some nonspecialists from taking on hep C patients. But hopefully, researchers can come up with easy-to-use risk calculators to take the guesswork out of prescribing DAAs for super-short periods.

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