Doctor details two new hepatitis C drugs

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In the last three weeks, the Food and Drug Administration has approved two new drugs that are expected to dramatically improve treatment of chronic hepatitis C, a liver-damaging viral infection that afflicts more than 3.2 million Americans.

Sovaldi (sofosbuvir), made by Gilead, and Olysio (simeprevir), made by Janssen Therapeutics, could improve cure rates while reducing serious side effects.

Jonathan M. Fenkel, a transplant hepatologist who directs Thomas Jefferson University's Hepatitis C Center, answered questions about the disease and the new drugs.

Question: How do you get hepatitis C and what does it do to the liver?

Fenkel: Hepatitis C is primarily a blood-borne infection, acquired through a contaminated blood transfusion, injection drug use, contaminated tattoo ink or needles, or accidental needlestick exposures. More than half of those infected with hep C in the U.S. are unaware they have it.

Because two-thirds of them are baby boomers - born between 1945 and 1965 - the Centers for Disease Control and Prevention recently recommended a hep C test for anyone born in those years.

Although a minority of people can spontaneously clear the infection without treatment, more than 80 percent develop chronic infection that

can lead to cirrhosis, liver failure, and liver cancer. Hep C-related liver failure is the most common reason for needing a liver transplant in the U.S.

Q: Until now, what was the standard treatment regimen, and how safe and effective was it?

A: The standard regimen included a combination of an injectable medication, pegylated interferon, and a pill, ribavirin. Treatment could take 24 to 48 weeks, depending on the genotype of hepatitis C. (There are at least six types of hepatitis C, called genotypes, that can be thought of like strains of the flu virus.) The chance of a cure ranged from 30 percent to 80 percent, depending on genotype and other factors like prior treatment. However, side effects are nearly universal and include fatigue, flulike symptoms, rash, depression, nausea, and diarrhea.

In 2011, the FDA approved the antiviral agents Victrelis (boceprevir) and Incivek (telaprevir) for patients with genotype 1. Taking one of these medications along with interferon and ribavirin doubled response rates and shortened treatment for some patients. But severe side effects with this triple therapy were common, patients had to take up to 12 additional pills daily, and patients with other genotypes were not eligible to take these new antivirals.

Q: How do the new drugs, Sovaldi and Olysio, work?

A: Both interfere with the hepatitis C virus' ability to replicate or grow in the body. Olysio is a protease inhibitor, like Incivek and Victrelis, but is just one pill a day. Although it still must be combined with ribavirin and interferon, most patients end treatment in 24 weeks. Sovaldi, the first polymerase inhibitor for hep C, is also taken with ribavirin and, for some patients, with interferon. Treatment is as short as 12 weeks. And for the first time, genotype 2 and 3 patients can have an interferon-free therapy

by taking Sovaldi with ribavirin.

Q: What are the side effects of the new drugs?

A: These drugs are far easier to tolerate than interferon and ribavirin. Fatigue, headache, and mild rash were among the reported problems, but few patients in the clinical trials stopped treatment due to side effects or adverse events.

Q: How are the new drugs expected to improve cure rates?

A: Cure rates are about 90 percent for regimens containing Sovaldi, and 80 percent for many regimens containing Olysio. Patients without underlying cirrhosis or being treated for the first time do best.

Q: The AIDS Healthcare Foundation and some other groups have expressed concerns about the costs of the new drugs. How expensive are they?

A: Sovaldi is reported to be $1,000 per day, or up to $84,000 for full treatment in genotype 1. Olysio's reported cost is nearly $800 a day, or $66,000 for full treatment. This is in addition to the cost of ribavirin or interferon, or both.

However, these prices are on a par with the costs of telaprevir or boceprevir, which payers have been covering. Also, the chance of cure is higher now, which could reduce the future costs associated with cirrhosis, liver failure, liver cancer, and liver transplantation. Still, I can definitely see cost being a barrier for some patients.

Q: Is this just the beginning of better treatments?

A: Yes. More than 20 drugs for hepatitis C may apply for FDA approval

in the next five years, and even more are in the pipeline. I predict that in five years, treatment will be combined in one daily pill, taken for 12 weeks or less, with a cure rate of more than 95 percent.

Q: What about the prospects for a vaccine?

A: Unlike hepatitis A or B, hepatitis C has no antibody for potential preventive vaccine to target. But successfully treating patients who are chronically infected will decrease the worldwide reservoir of the hepatitis C virus and decrease the need for a preventive vaccine.