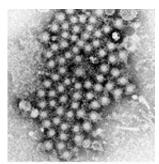


More drugs show promise in fighting hepatitis C

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Electron micrograph of hepatitis virus. Source: US Centers for Disease Control and Prevention

Faldaprevir and deleobuvir are part of effort to develop treatments that avoid harsh side effects.

(HealthDay)—An experimental drug duo may cure some cases of the liver disease hepatitis C, without the severe side effects of standard therapy, a new clinical trial suggests.

The study, of 362 people with chronic <u>hepatitis</u> C, found that the <u>new drugs</u>—combined with one older drug—cleared the virus from up to 69 percent of patients. And that was without having to use interferon, a difficult-to-take injection drug that is part of the current therapy.

Experts said the findings, published in the Aug. 15 issue of the *New England Journal of Medicine*, are another step forward in vastly



improving hepatitis C treatment.

Dozens of drugs are in development, and some are currently being considered for approval by the U.S. Food and Drug Administration (FDA).

"These are very exciting times in hepatitis C treatment," said Dr. Michael Saag, an infectious disease specialist at the University of Alabama at Birmingham who was not involved in the new study.

Hepatitis C is a <u>liver infection</u> usually passed through contact with infected blood. For most people, the infection becomes chronic, which can eventually lead to scarring of the liver (cirrhosis) or <u>liver cancer</u> years later.

That happens only in a minority of people. "But we have no way of knowing in advance who will develop cirrhosis or cancer," Saag said.

The current <u>drug regimen</u> for chronic hepatitis C includes interferon, plus an older oral drug called ribavirin, and either one of two drugs just approved in the last couple of years, called telaprevir and boceprevir. That combo cures about 68 percent to 75 percent of people with the most common strain of hepatitis C, called genotype 1.

The problem is, treatment lasts for months and almost always causes substantial side effects.

Interferon is especially hard to take, with side effects ranging from <u>sleep problems</u> and <u>mood swings</u>, to nausea and diarrhea, to muscle pain, fever and fatigue.

"There is a great desire to be able to cure hepatitis C without interferon," said Saag, who also serves on the Infectious Diseases Society of



America's hepatitis task force.

In the new study, funded by drugmaker Boehringer Ingelheim, German researchers tested two experimental drugs called faldaprevir and deleobuvir against hepatitis C genotype 1.

The investigators randomly assigned 362 patients to one of five groups. Each group received the two new drugs. Four groups also took ribavirin, while the fifth did not.

In the end, the ribavirin proved necessary, Saag pointed out. Three months after their treatment ended, anywhere from 52 percent to 69 percent of patients on all three drugs were hepatitis free, depending on the dose and how long they took the medications.

In contrast, only 39 percent of patients who did not take ribavirin were free of the virus.

The benefits also depended on which virus subtype patients had. Of those with genotype 1b, up to 85 percent were hepatitis free three months after treatment. That compared with no better than 47 percent of patients with type 1a.

"That's to be expected," Saag said. "Type 1b is just easier to treat in general."

There are still questions, and later-stage trials of the new drugs are continuing, said study leader Dr. Stefan Zeuzem, of Goethe University Medical Center, in Frankfurt.

The ideal treatment time, for example, is not clear. The study patients took the drugs for 16 to 40 weeks. But for patients with type 1b, 16 weeks might be enough, according to Zeuzem.



That compares with up to 48 weeks with standard treatment.

As for side effects, nearly all of the study patients had some, including rash, nausea, vomiting and diarrhea. But for most, those problems were mild, Zeuzem's team noted.

"Interferon side effects are certainly worse than side effects observed with faldaprevir and deleoprevir," Zeuzem said.

"It looks like severe <u>side effects</u> were not common," Saag agreed. But, he said, "the main problem with these drugs is that you still have to use ribavirin."

Ribavirin is more tolerable than interferon, but it destroys red blood cells and can cause serious fatigue and other problems.

"Ideally, you'd like drug regimens without ribavirin," Saag said. The good news, he added, is that those are on the way.

Between 50 and 60 new hepatitis C drugs are currently in the pipeline, Saag said, and a couple are already under review by the FDA. One is sofosbuvir: In a recent trial, researchers found that sofosbuvir, along with ribavirin, cured about three-quarters of patients with genotype 2 or 3 hepatitis C.

But Saag predicted that in the next year or two, there will be <u>oral drug</u> regimens that bypass interferon and ribavirin altogether.

"There should be a lot of new options for hepatitis C patients in the next couple years," he said. These new findings, Saag added, "are an important step. But they are not the final step."

In the United States, an estimated 3.2 million people are living with



chronic hepatitis C—most of whom do not know it. Because of that, the U.S. Centers for Disease Control and Prevention recommends that baby boomers (people born between 1945 and 1965) be tested for the virus.

Injection <u>drug</u> abuse is now the top risk factor. But people who had a blood transfusion before 1992 are also at risk, because that predated widespread hepatitis C screening. In a small number of cases, the virus is transmitted during sex.

More information: The U.S. Centers for Disease Control and Prevention has more on <u>hepatitis C</u>.

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