

Treatment for advanced hepatitis C doesn't work, researchers find

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An NIH funded multi-center clinical trial found no benefit from "maintenance therapy," low-dose peginterferon used for hepatitis C patients who have not responded to an initial round of treatment. In addition, the study showed a surprising health decline in patients with liver disease over the course of four years.

A Saint Louis University researcher was lead author and chairman of the study, which will be published in the Dec. 4 issue of the *New England Journal of Medicine*. The study ruled out low-dose peginterferon maintenance therapy as a treatment for patients with advanced chronic hepatitis.

"This course of treatment had been adopted by a number of doctors in the U.S. and in other countries, though it had yet to be proven to work. That practice should be stopped based on the results of this trial. There is no rationale for using maintenance therapy," said Adrian Di Bisceglie, M.D., professor of internal medicine, chief of hepatology and co-director of the Liver Center at Saint Louis University. "The treatment is clearly ineffective."

About 4 million people in the U.S. have been infected with hepatitis C; an estimated 10,000 to 12,000 people die from complications each year in this country. Hepatitis C is caused by a virus, transmitted by contact with blood, and may initially be asymptomatic. For patients who develop a chronic hepatitis C infection, inflammation of the liver may develop, leading to fibrosis and cirrhosis (scarring of the liver), as well as other

complications including liver cancer and death.

For patients with chronic hepatitis C, the prognosis varies. About half fully recover after an initial course of peginterferon and ribavirin anti-viral therapy that may last from six months to a year.

The remaining patients, known as non-responders, may improve but the virus is not eliminated. Researchers studied these patients, looking at those with advanced liver disease as identified by liver biopsies that showed advanced scarring. These patients were at greatest risk for worsening.

The study looked at 1050 patients at 10 different clinical sites.

Researchers gave patients peginterferon for three and a half years, but in lower doses to try to suppress but not eliminate the virus, with the hope of slowing the dire consequences of liver disease. Half of the patients were treated with a low dose of peginterferon and half were put into a control group for a total of four years.

The results were clear; maintenance therapy did not stop liver disease from progressing.

In addition, researchers were startled by the rate of progression of liver disease. After four years, 30 percent of the patients in both the treatment and control groups had developed liver failure, liver cancer, or had died. Among those with milder cirrhosis, 10 to 12 percent developed severe liver disease, also unexpected.

"Hepatitis patients in these circumstances got very ill over the course of four years, surprisingly so," said Di Bisceglie. "The lesson we learned is that once chronic hepatitis C gets to the stage of advanced fibrosis, patients can decline rapidly."

As doctors look to the future, their hope rests on new drugs that are currently in clinical trials.

Source: Saint Louis University

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