Interferon as long-term treatment for hepatitis C not effective

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Use of the drug interferon as a long-term maintenance strategy to slow the progression of liver disease associated with the hepatitis C virus is ineffective, UT Southwestern Medical Center researchers and their colleagues from nine other institutions have found in a multicenter study.

Results of the 3½-year study, called the HALT-C (Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis) Trial, appear in today's issue of *The New England Journal of Medicine*. The researchers found no difference in the rate of progression of liver disease among patients who received interferon and those who did not.

"It wasn't that there was an insignificant difference; there was absolutely no difference whatsoever in the progression to cirrhosis and other disease complications," said Dr. William M. Lee, professor of internal medicine at UT Southwestern and a principal investigator for the study. "It is a negative study but an important one."

Dr. Lee said physicians should not expect any benefit from the long-term use of interferon by itself in slowing disease progression. By contrast, use of interferon with other drugs such as ribavirin can lead to viral eradication, or complete clearance of hepatitis C virus, a result that will "stop the disease in its tracks," Dr. Lee said.

Hepatitis C is a viral infection that causes liver inflammation and can progress over many years to cirrhosis, liver cancer, liver failure and death. The disease affects more than 3 million people in the United States and 170 million people worldwide. It is the most common reason for liver transplantation in the U.S.

There is no vaccine to prevent hepatitis C virus infection. The combination of interferon and ribavirin works for about 40 percent to 50 percent of people with the virus, while the other 50 percent to 60 percent of patients will continue to progress to later states of liver disease, Dr. Lee said.

In addition to interferon and ribavirin, new drug agents such as protease and polymerase inhibitors are being used in clinical studies at UT Southwestern to improve rates of virus eradication. Food and Drug Administration approval of these agents is likely to be three years away, Dr. Lee said.

In the HALT-C Trial, conducted between August 2000 and June 2007, 1,050 people with hepatitis C who did not respond to initial antiviral treatment were assigned randomly to either a group that received treatment with a type of interferon called peginterferon or to a group that did not. About 120 patients were enrolled at UT Southwestern.

Participants were monitored every three months and underwent liver scans and biopsies at specified intervals through the study period. Researchers found that although the level of hepatitis C virus in blood and certain enzymes in the liver decreased significantly with treatment, there was not a significant difference in ultimate clinical outcome.

"Currently, we use interferon only to clear the virus," said Dr. Lee. "If you cannot clear the virus with treatment, the idea that struggling long term through the side effects of interferon is somehow going to help you rid yourself of cirrhosis is just not plausible any longer."

Some patients cannot tolerate the side effects of the different types of interferon medication, which can cause extreme flu-like symptoms, such as fever, chills, fatigue, depression, muscle aches, chest pain, difficulty breathing, nausea, vomiting, and weight and hair loss.

Source: UT Southwestern Medical Center