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Combination therapy offers quicker, less toxic eradication of hep C in liver transplant patients

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All patients with hepatitis C who receive a liver transplant will eventually infect their new livers. These transplanted organs then require anti-viral treatment before they become severely damaged. But traditional post-transplant hepatitis C therapy can take up to a year, is potentially toxic and can lead to organ rejection.

Now, at the American Association for the Study of Liver Diseases (The Liver Meeting 2014) in Boston, researchers at Mayo Clinic report that use of two new oral medications post-transplant is safe and beneficial, and requires only 12 weeks of treatment.

"This is the first study to examine the use of these two new drugs—simeprevir and sofosbuvir—in liver transplant recipients, and, based on this large study, we find it to be a better option than current treatment," says the study's lead researcher, Surakit Pungpapong, M.D., a transplant hepatologist and an associate professor of medicine at Mayo Clinic in Florida.

Standard pre- and post-transplant treatment requires the use of interferon injections, along with ribavirin. Interferon engages the human immune system to fight the hepatitis C virus, but this immune response can also lead to organ rejection, Dr. Pungpapong says. Interferon can cause a variety of side effects, including anemia, depression, irritability, flu symptoms, insomnia, and hair loss, among others, he says.

Given the clinical importance of the study, results are being presented at the meeting in a plenary session.

Chronic hepatitis C virus is the most common chronic bloodborne infection in the United States, affecting more than 3 million individuals. Most infected people have no symptoms of the disease until liver damage from chronic inflammation occurs decades later—which happens to 5-30 percent of infected individuals. Hepatitis C infection accounts for two-thirds of newly diagnosed chronic liver disease cases and 40 percent of liver transplants.

For this study, Mayo Clinic researchers enrolled post-transplant patients at their three sites, including Rochester, Minnesota, Scottsdale, Arizona and the Mayo Clinic Transplant Center in Jacksonville, Florida, which has one of the five most active liver transplants programs nationwide. Researchers will report on outcomes of more than 100 patients, but the study is still ongoing.

These patients were too sick to be treated for hepatitis C before their transplant, says Dr. Pungpapong. "By the time liver cirrhosis occurs, it could be too late to use anti-viral drugs," he says.

Simeprevir and sofosbuvir were approved for pretransplant use last year by the Food and Drug Administration (FDA), but not as a combined therapy. The FDA also required that they be combined with interferon and ribavirin.

But in a large clinical trial, researchers tested simeprevir and sofosbuvir without interferon—an off-label use—in pretransplantation patients and found the combination to be a brief and effective therapy. In this study, the Mayo researchers extended the idea of using these drugs together without interferon in post-transplantation patients.

The researchers found that eradication of the virus in the patients was excellent—more effective than the use of interferon and ribavirin—and with much fewer side effects. "We believe use of these drugs, both pre- and post-transplant represents a substantial clinical advance," Dr. Pungpapong says.

Provided by Mayo Clinic