New treatment option for patients with chronic hepatitis C

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A new combination therapy of daily consensus interferon (CIFN) and ribavirin is effective for some people with chronic hepatitis C (HCV) who do not respond to standard therapy. The treatment works particularly well in interferon-sensitive patients who have lower fibrosis scores, according to a new study in the June issue of *Hepatology*, a journal published by John Wiley & Sons on behalf of the American Association for the Study of Liver Diseases (AASLD).

Nearly half of all HCV patients do not respond to the standard therapy of pegylated interferon and ribavirin. They remain at risk for developing life-threatening liver disease. So far, other alternative therapies have not been particularly successful in these nonresponders.

One new treatment with the potential to help patients with persistent HCV involves high doses of daily consensus interferon (CIFN) combined with ribavirin. Researchers, led by Bruce Bacon of St. Louis University, conducted a multicenter trial to examine the efficacy, tolerability and safety of this approach.

The researchers studied 487 patients whose HCV had not responded to initial treatment with standard therapy. Many had characteristics that generally bode poorly for treatment response. Nearly all had HCV genotype 1; 80 percent had not responded strongly to their previous treatment; 68 percent had high baseline levels of the virus in their blood; 60 percent had advanced liver disease; and about 20 percent were African-American. These factors have all been shown to reduce rates of

sustained viral response after treatment.

The patients were divided into three groups. Two would receive the new therapy at different doses, and the third would receive no therapy. After 24 weeks, the control group was stratified into one of the treatment arms.

Ultimately, 245 of the patients received 9 mcg of CIFN daily along with ribavirin, and 242 others took 15 mcg of CIFN daily along with ribavirin. After 24 weeks, patients with detectable HCV RNA were considered non-responders and stopped the therapy. Responders continued taking their therapy up through week 48, and were then followed-up through week 72. If HCV RNA was detected between weeks 48 and 72, the patient was classified as a relapser.

Nearly 7 percent of the patients taking 9 mcg of CIBN, and 10.7 percent of those taking 15 mcg, achieved a sustained viral response. The rates were even higher among patients who had responded better to the standard therapy and among those who had lower baseline fibrosis scores.

"The best response rate, 31.6 percent, was observed in noncirrhotic patients who had a partial virologic response with a greater than 2-log10 decline in HCV RNA during their previous course of peg-IFN treatment," the authors report.

While adverse events were common, most patients continued their treatment in spite of them. Common side effects were neutropenia, fatigue, leucopenia, depression, nausea, muscle pain, lymphopenia and anemia.

"The present study demonstrated that some patients with chronic hepatitis C who have failed to respond to treatment with peg-IFN and

RBV can be successfully retreated with daily CIFN and RBV," the authors conclude. "The greatest SVR rate during retreatment in the present study was observed in F0-F3 patients who had a partial virologic response during their prior course of treatment."

More information: "Retreating Chronic Hepatitis C with Daily Interferon Alfacon-1/Ribavirin after Nonresponse to Pegylated Interferon/Ribavirin: DIRECT Results." Bacon, Bruce R.; Shiffman, Mitchell; Mendes, Flavia; Ghalib, Reem; Hassanein, Tarek; Morelli, Giuseppe; Joshi, Shobha; Rothstein, Kenneth; Kwo, Paul; Gitlin, Norman. *Hepatology*; June 2009.

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