Hep C Treatment Effective in HIV Patients With Normal Liver Enzymes

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People infected with HIV and hepatitis C virus (HCV) who have normal liver alanine transaminase (ALT) levels may benefit from pegylated interferon/ribavirin treatment, according to new data presented Tuesday, July 21, at the XVIII International AIDS Conference in Vienna. These results are important, as people with HCV and normal ALT levels are frequently told that treatment is not necessary.

As explained by Miguel Angel Von Wichmann, MD, of the Hospital Donostia in Madrid, normal ALT levels in the setting of chronic HCV infection are typically considered a factor related to slow progression to end-stage liver disease. However, he said, 80 percent of people with chronic HCV and normal ALT levels eventually develop some degree of liver disease, including significant progression to fibrosis and the development of liver cancer.

At least one study in people infected with HCV, but not HIV, has demonstrated that sustained virologic responses (SVRs)—an undetectable viral load maintained for at least six months after discontinuing treatment—are comparable among those with normal ALT levels versus those with elevated ALT levels. Whether this observation also holds true for people coinfected with HIV and HCV has, until now, been virtually unknown.

Von Wichmann and his colleagues conducted a study involving 68 HIV/HCV coinfected patients, divided into two groups. The first group included 35 patients with at least five normal ALT values over a 24-month period; the second group included 33 patients with persistently elevated ALT levels. All patients received pegylated interferon plus ribavirin (1,000 to 1,200 mg a day).

Twenty-four weeks of data from the 72-week study were presented by Von Wichmann in Vienna. Patients were, on average, 43 years old at the time of study enrollment; 77 percent were men. Roughly 74 percent had HCV genotypes 1 or 4—the most difficult to treat—and slightly more than half of the patients in each group had high HCV viral loads (greater than 800,000). Most patients had undetectable HIV viral loads.

SVR rates will not be known until therapy is discontinued at week 48 and the week-72 follow-up period has been reached. Von Wichmann reported, however, that early virologic responses (EVRs) were comparable between the two groups.

About 52 percent of case patients, compared with 68 percent of control patients, had undetectable HCV viral loads after 12 weeks of treatment—both encouraging results believed to be highly predictive of SVRs once treatment is discontinued. But it's important to note that the difference between the two groups was not statistically significant, meaning it could have been due to chance.

Another measure of EVR—a greater than 2-log reduction in HCV viral load—was also reported. This was documented in 80 percent of the case volunteers and 96.4 percent of the control volunteers. Again, the difference was not found to be statistically significant.

The incidence of moderate-to-severe side effects, including hair loss, white blood cell decreases, flu-like symptoms, chest pain and weakness, was similar in both groups—roughly 46 percent.

At week 24, people in the group had higher CD4s: 300 cells versus 224.5 cells in the control group. Though this difference was statistically significant, it is also worth pointing out that patients in the case group tended to have higher CD4s upon entering the study (557 cells), compared with controls (409.5 cells).

Not surprisingly, ALT levels decreased in both groups, with those in the case group maintaining ALT levels significantly lower than those in the control group.

"These preliminary data," Von Wichmann's group concluded, "suggest that combination pegylated interferon and ribavirin in HIV-HCV coinfected patients with persistently normal ALT levels achieves comparable response values to patients with elevated ALT, with an adequate safety profile. Further analysis are needed to confirm these data and support the use of pegylated interferon plus ribavirin in these patients in clinical practice."
