

Head-to-head studies identify best treatment regimen for hep C

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In patients with chronic hepatitis C, treatment with peginterferon alpha-2a (PegIFN α 2a) plus ribavirin (RBV) better suppresses the virus to undetectable levels in the blood than treatment with peginterferon alpha-2b (PegIFN α 2b) plus RBV, according to two new head-to-head studies in *Gastroenterology*, the official journal of the American Gastroenterological Association (AGA) Institute.

Patients with chronic [hepatitis C](#) virus (HCV) infection are frequently treated with a combination of peginterferon, either PegIFN α 2a or PegIFN α 2b, and RBV. In fact, this combination, which is the treatment of choice, has increased sustained virological response (SVR) rates from less than 20 percent to more than 60 percent. Obtaining complete SVR is the goal of treatment for HCV; patients who experience SVR for more than six months often do not experience disease relapse.

While previous trials have demonstrated that both pegylated interferons are effective and safe when administered with RBV, only two randomized clinical studies have compared the efficacy of the peginterferon formulations, neither of which was sufficiently powered to detect a statistically significant difference in SVR rates.

"Head-to-head trials comparing the efficacy and safety of PegIFN α 2a or PegIFN α 2b in combination with RBV in the treatment of patients with [chronic hepatitis C](#) are needed," said Massimo Colombo, MD, of the University of Milan and author of one of the head-to-head studies published in *Gastroenterology*. "There is insufficient evidence to support

conclusions that one therapeutic regimen is superior to the other one."

In the first study, previously untreated patients with chronic hepatitis C were randomly assigned after stratification for HCV genotype to either RBV combined with PegIFN α 2a or PegIFN α 2b for 24 or 48 weeks, according to virus genotype. Researchers found that overall, the SVR rate was significantly higher in PegIFN α 2a than in PegIFN α 2b (66 percent versus 54 percent).

"Whether our strategy of RBV dosing, which is at variance with the standard of care for PegIFN α 2a treatment, is indeed cost-effective, needs to be prospectively assessed through a pharmaco-economy study," added Dr. Colombo.

Similar results were reported in a second study published in *Gastroenterology*. In this single-center, randomized, head-to-head study, 320 consecutive, treatment-naïve, HCV-RNA-positive patients with chronic hepatitis were randomly assigned to groups given once-weekly subcutaneous PegIFN α 2a or PegIFN α 2b plus RBV 1,000 mg/day or 1,200 mg/day for 48 weeks or 24 weeks. More patients in the PegIFN α 2a group than the PegIFN α 2b group achieved SVR (68.8 percent versus 54.4 percent).

In fact, study authors found that in patients with chronic HCV infection, treatment with PegIFN α 2a plus RBV produced a significantly higher SVR rate than treatment with PegIFN α 2b plus RBV; the safety profile of the two regimens were similar.

"The fact that both of these studies yielded similar and significant results confirms the potential advantages of PegIFN α 2a plus RBV versus PegIFN α 2b plus RBV," said Antonio Ascione, MD, of Fatebenefratelli Hospital in Naples and lead author of this study. "These advantages may translate to the development of promising new direct anti-viral drugs

against HCV."

More information: i Rumi M et al. Randomized Study of Peginterferon- α 2a Plus Ribavarin vs Peginterferon- α 2b Plus Ribavarin in Chronic Hepatitis C. *Gastroenterol* 2010;138:108-115.

ii Ascione A et al. Peginterferon Alpha-2a Plus Ribavirin Is More Effective Than Peginterferon Alpha-2b Plus Ribavarin for Treating Chronic Hepatitis C Virus Infection. *Gastroentrol* 2010;138:116-122.

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