Hepatitis C: No overall difference in sustained viral response in most widely used treatments

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Findings from the largest study to date comparing the efficacy of competing treatments for chronic hepatitis C infection (HCV) show that the regimens are similar when it comes to safety and their ability to provoke long-term viral eradication, according to researchers at Duke University Medical Center. Still, subgroup analysis reveals provocative data suggesting some approaches might be better than others for women and minorities.

The study findings may be helpful for the estimated 170 million people world-wide who have been diagnosed with hepatitis C as well as the physicians who treat them. Hepatitis C is a major health problem that can lead to liver disease and sometimes death. Recently, there has been considerable controversy over which treatment options are the most effective - and the makers of the various medications have a lot at stake. Analysts estimate the U.S. prescription market for hepatitis C to be approximately $3 billion annually.

Treatments for hepatitis C are notoriously difficult, and sometimes the side effects are so debilitating that patients decide to stop therapy rather than endure the consequences. In addition, treatments are curative in less than half the people who receive them.

Current guidelines recommend a combination of peginterferon with the antiviral ribavirin for 48 weeks, "but no one has really compared the therapies prospectively and adequately until now," says John McHutchison, M.D., Associate Director of the Duke Clinical Research Institute and the lead author of the study appearing online in the New England Journal of Medicine.

Investigators at 118 sites randomly assigned 3070 patients with HCV genotype 1 to one of three treatment regimens. They compared a standard dose of peginterferon alfa-2b (Pegintron) with a low dose of peginterferon alfa-2b (Pegintron) combined with ribavarin, and a standard dose of peginterferon alfa-2a (Pegasys) also with ribavarin.

Peginterferon alfa-2b is marketed by Schering-Plough as Pegintron. Peginterferon alfa-2a, is marketed as Pegasys by Roche.

They found that no treatment proved superior in achieving a sustained viral response.

Response rates were 39.8 percent, 38.0 percent and 40.9 percent, for the Pegintron standard dose, Pegintron low dose with ribavarin and Pegasys with ribavarin regimens, respectively. The study compared regimens, not the competing types of peginterferon directly.

There was significant variation among relapse rates, with 23.5 percent, 20 percent and 31.5 percent of the patients relapsing in the Pegintron standard dose, Pegintron low dose with ribavarin and Pegasys with ribavarin regimen respectively.

"Patients receiving the peginterferon alfa-2a (Pegasys) treatment were significantly more likely to relapse, but at this point, we do not know why," says McHutchison.

Researchers also noted that similar numbers of participants in each arm of the trial suffered similar incidences of serious side effects (percentages ranged from 9.3 percent in the low dose Pegintron group to 11.7 percent in the Pegasys group) and that patients in the low dose Pegintron group were significantly less likely to drop out of treatment because of any side effects.

McHutchison says they were surprised to find no significant difference in response between the

standard and low dose arms of the Pegintron arms of the study. He says a dose reduction of Pegintron that may be required to manage side effects will not negatively influence response and that the finding does not automatically translate into a recommendation of the initial lower dose approach for everyone.

"When we evaluated subgroup analyses, we found other interesting findings. For example, it appears that women do significantly better if they receive the standard dose, rather than the low dose of peginterferon alfa-2b (Pegintron). African Americans also tended to do better with the standard dose peginterferon alfa-2b (Pegintron) therapy, although the relationship was not statistically significant."

McHutchison says one of the more interesting findings from the study is that patients' response as early as four weeks after initiating therapy appeared to be a robust predictor of overall success. "We found that a steep decline and eradication of viral levels at one month after starting treatment was a powerful predictor of sustained viral suppression six months after treatment ended." McHutchison also says that only about 5 percent of patients who had a weak response by the end of the first month managed to achieve a sustained viral response.

McHutchison says the study has several limitations. First, because of the way the medications are formulated, patients and doctors were aware of the type of peginterferon they were getting, so the study was not fully blinded. Also, despite overall response rates being equivalent in half the study population who received equivalent doses of ribavirin combined with peginterferon, the ribavirin dosing schedules differed between the regimens. Therefore, the study only compares regimens, and not the competing types of peginterferon. In addition, the findings should not be generalized to patients who have other HCV genotypes; the study was confined to only those with HCV genotype 1, the most common genotype in the U.S. and Europe.

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