Hepatitis C Treatment: A Look at Generics and the Real World

November 15, 2016 By Lucinda K. Porter RN

This week I am discussing some of the research presented at this year's Liver Meeting in Boston; here are two that I thought were interesting. Note that conference presentations are preliminary investigations, and need to be published in a peer-reviewed journal before data can be considered conclusive.

Abstract #890 High Sustained Virological Response Rates Using Legally Imported, Generic Direct Acting Antiviral Treatment for Hepatitis C – James A. Freeman, et al.

For a variety of reasons, some hep C-positive people are unable to get access to hepatitis C treatment. The cost of hep C drugs is a huge, and all to common obstacle to care. Patients confronted with this sometimes obtain generic hep C medications from other countries, which cost about one percent of the retail price in the United States. However, generics have not been well studied, and this research examined the efficacy of generic hep C treatments.

Sofosbuvir (SOF), ledipasvir (LDV) and daclatasvir (DCV) were legally imported from generic companies in India, China and Bangladesh. The generics underwent analysis and deemed safe prior to initiating therapy. Patients were prescribed treatment according to genotype and fibrosis stage. Data were collected from 481 subjects.

Conclusions: Overall, generic direct-acting antivirals (DAAs) achieved SVR12 rates of 91 percent, comparable to those seen in Phase 3 trials of the branded treatments.

Editorial Comments: James Freeman and others (including HEP blogger and study co-investigator, Greg Jefferys) have done much to legitimize the use of generic hepatitis C medications, and this study fortifies the option of legally obtained and tested generic hepatitis C drugs.

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Abstract #892 Real World Effectiveness of Ledipasvir/Sofosbuvir (LDV/ SOF) in Patients Coinfected With HCV and HIV-1: A Comparative Analysis of Clinical Trials with Four Real World Cohorts – Susanna Naggie, et al.

In the days when interferon was the backbone of hepatitis C virus (HCV) treatment, people who

were coinfected with HIV/HCV had lower treatment success rates. However, in studies of treatment using direct-acting antivirals (DAAs) in coinfected patients, success rates are comparable. This study analyzed the HCV success rates of coinfected patients who were treated in real world circumstances, rather than in clinical trials. The study enrolled 445 genotype 1 patients from 4 centers in the U.S. and Europe. Everyone was treated with ledipasvir/ sofosbuvir.

Conclusion: The treatment success rates of HIV/HCV co-infected patients in the real world was comparable to the rates seen in clinical trials. These rates were comparable regardless of race or prior treatment experience and cirrhosis.

Editorial Comments: With this and other data, there are clear indications of the power of DAAs to cure hepatitis C, regardless of comorbidities (such as HIV), genotype, race, ethnicity, and use of substances. The presence of cirrhosis is still a problem, but this can be solved by offering early treatment and improved hep C treatments.

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