Hepatitis C treatment less effective in urban minority patients

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A recent study confirms that the standard hepatitis C (HCV) therapy, pegylated interferon and ribavirin, is significantly less effective in urban minority patients treated in an ordinary clinical practice setting compared with results produced during clinical trials. Results of this study appear in the April issue of *Hepatology*, a journal published by Wiley-Blackwell on behalf of the American Association for the Study of Liver Diseases.

According to the CDC's Office of Minority Health & Health Disparities (OMHD), minorities experience a disproportionate burden of preventable disease, death, and disability compared with non-minorities. Groups currently experiencing poorer health status are expected to grow as a proportion of the total U.S. population. African Americans have higher rates of HCV and hepatitis B (HBV) infection than whites or Hispanics, while hepatitis A (HAV) rates are higher among Hispanics than among non-Hispanics. Current information about the biologic and genetic characteristics of minority populations does not explain the health disparities experienced by these groups compared with the white, non-Hispanic population in the U.S. These disparities are believed to be the result of the complex interaction among genetic variations, environmental factors, and specific health behaviors.

A study conducted at the Albert Einstein College of Medicine supports the disparity in drug efficacy among various minority populations. Researchers analyzed combination pegylated interferon and ribavirin, which has proved an effective treatment regimen for HCV in clinical

trials, but doesn't yield the same success rates in daily clinical practice, particularly with minority patients. Study leader Dr. John F. Reinus explains, "Industry-sponsored trials are conducted with the advantage of extraordinary resources to ensure that all aspects of therapy with a study drug are accurately controlled, observed and documented."

Researchers noted that because Hispanics and African-Americans are underrepresented in clinical trials, the results do not necessarily reflect how trial drugs will affect these patients. In fact, studies have shown that African-American and Hispanic patients infected with HCV are less likely to have a sustained viral response (SVR) to treatment compared to non-Hispanic whites. Nevertheless, efficacy data from randomized controlled therapeutic trials are commonly used to make important treatment decisions. "Practitioners need to know not only the efficacy of combination therapy as demonstrated in phase-III registration trials, but also its effectiveness: the outcome of treatment in patients like their own receiving ordinary clinical care," Dr. Reinus says.

Patients were seen in the private Faculty Practice of the Albert Einstein College of Medicine or the attending-supervised Liver Clinic at Montefiore Medical Center, Bronx, New York. Patients in both settings had the same liberal access to treating physicians and their therapy was similarly supported by ancillary services. These resources were felt to equal or exceed in quality and availability those accessible to non-hospital-based private-practice patients. In addition, the same aggressive approach to side-effect management was used in both practice settings, and dose reductions were avoided unless drug side effects could be managed in no other way.

A total of 255 HCV patients were evaluated. The majority of study patients were Hispanic (149), followed by African-American (52), other (31), and Caucasian (23). One-hundred thirty-one patients (51%) completed treatment and SVR was achieved in 54 patients, of whom

63% were Hispanic, 8% were African-American, and 17% were Caucasian. By contrast, multinational phase-III randomized controlled trials of HCV therapy with combination pegylated interferon and ribavirin, intention-to-treat analysis has consistently shown SVR rates of 54 to 63%.

"Published reports suggest that therapy is less effective in urban HCV patients than in persons enrolled in registration trials, which include mostly patients of western-European ancestry, Dr. Reinus says. "This hypothesis is confirmed by our data: the overall SVR rate in our patients was one-third to less than one-half that predicted on the basis of registration trials. This discrepancy does not appear to be accounted for by other factors, including patient demographics and features of infection. We conclude that new strategies are needed to care for such patients."

More information: "Effectiveness of Hepatitis C Treatment with Pegylated Interferon and Ribavirin in Urban Minority Patients." Paul Feuerstadt, Ari L. Bunim, Heriberto Garcia, Jordan J. Karlitz, Hatef Massoumi, Amar J. Thosani, Andrew Pellecchia, Allan W. Wolkoff, Paul J. Gaglio, John F. Reinus. Hepatology; Published Online: November 13, 2009 (DOI:10.1002/hep.23429); Print Issue Date: April 2010.

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