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a series of fact sheets written by experts in the field of liver disease

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HCSP FACT SHEET

•HCV POPULATIONS•

African Americans and Hepatitis C

Written by: Alan Franciscus, Editor-in-Chief

Foreword

There are clear differences in terms of chronicity, disease progression, and treatment response rates among different ethnic and racial groups with regard to hepatitis C. Nowhere are these differences more pronounced than in the African American population when compared with other racial or ethnic groups with hepatitis C. For instance, African Americans are more likely to have been exposed to HCV and are less likely to resolve acute HCV infection compared to other racial/ethnic groups. There are some studies that suggest that African Americans may have slower natural HCV disease progression. The reasons for these differences are largely unknown because African Americans have not been adequately represented in clinical trials. There have been two studies, however, that have shed some light on these important questions—Virahep-C sponsored by the National Institutes of Health and Genentech and recent findings from studies of a variation of a certain gene called IL28B.

HCV Infection in African Americans

African Americans are more than twice as likely to have been infected with HCV than Caucasians. It is conservatively estimated that approximately 4.1 million Americans have been infected with hepatitis C, and that of those 3.9 million are chronically infected with HCV. The prevalence of HCV in the African American population is estimated at about 3% which is higher than in non-Hispanic whites (1.2%) and Hispanics (1.3%). The reasons for the higher rate of infections are not completely understood, but there is some speculation that African Americans are at greater risk for contracting HCV through occupational exposure (an estimated 3 million African Americans are employed as health care professionals), blood transfusions (which may be required to treat sickle cell anemia, which mostly affects African Americans), or through a documented higher prevalence of injection drug use. In addition, various studies have found that African Americans as a group have less access to information on HCV and preventative medical care.

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Information on Hepatitis

HCV diagnosis and prevention measures require access to information about hepatitis C. It is clear that information about HCV has not effectively reached the majority of African Americans in this country. A public awareness poll conducted by the American Liver Foundation found that compared with the general public, African Americans are not as aware of the risk factors or symptoms of hepatitis C. In addition, a media analysis discovered that there has been little news coverage of hepatitis C in the African American press, which is a trusted resource and plays a critical role in informing the African American community.

Chronic HCV Infection among African Americans

In the general population, 55% to 85% of individuals exposed to HCV become chronically infected. This rate is much higher in African Americans (87 to 95%) than in Caucasians (66-67%). Part of the reason for the higher rate of chronic infection in African Americans can be attributed to the lack of a certain genetic variation in the IL28B gene – part of our body's natural immune system.

HCV Genotype

In the United States, genotype 1 accounts for approximately 70-75% of all HCV infections, followed by genotypes 2 and 3, which together account for approximately 30% of infections. In the African American population, however, genotype 1 accounts for 91% of infections – compared to 67% in Caucasians. Before the approval of HCV protease inhibitor triple therapy, genotype 1 was more difficult to successfully treat; this had important implications for HCV medical treatment response rates, and explained some, but not all of the disparities in treatment response rates among African Americans compared with other racial and ethnic groups.

Natural Disease Progression

The rate of natural disease progression in African Americans has been widely debated. Two retrospective studies (based on medical records, looking backward in time at events that happened in the past) have found that there are differences in the natural disease progression in African Americans compared to other groups, but the studies have also raised many questions.

Dr. Thelma E. Wiley and colleagues reviewed the medical records of 355 people infected with HCV from 1996 through 1999, of whom approximately 32% were African Americans. The participants in the study were similar with regard to the mode of transmission and HCV RNA (viral load) levels, but the African Americans were older and had been infected with HCV for longer periods compared with the non-African American participants. Levels of alanine aminotransferase (ALT, an enzyme released when the membranes of liver cells break down causing inflammation and cell death) are frequently lower in African Americans than in the general population, as was seen in this study population. Genotype 1 was more prevalent among African Americans (88% versus 67%) than the other groups in this study, which is consistent with recognized patterns.

The authors found that the rate of natural HCV disease progression was significantly lower in African Americans compared with Caucasians. After the second decade of HCV infection, 0% of African Americans in the study progressed to stage 4 cirrhosis compared with 26% of whites; in the third decade, the respective rates were 18% versus 31%, and in the fourth decade the rates were 33% versus 47%. The authors concluded that HCV infection in African Americans progresses at a slower rate than in non-African Americans. Even though similar data were reported by researchers from the University of Southern California at Los Angeles, it is difficult to draw concrete conclusions, since both studies were retrospective, which could bias the results.

However, even allowing for potential bias, these findings suggest that African Americans may progress to cirrhosis more slowly than Caucasians. These results need to be confirmed by larger prospective studies. And if these data are confirmed by future research, the reasons for the difference in disease progression may also be elucidated.

Treatment Response - History

VIRAHEP-C Clinical Trial of African Americans with HCV

African Americans comprise 22% of Americans with hepatitis C – but account for about 10% of participants in HCV clinical trials. In 2002 the National Institute of Diabetes and Digestive and Kidney Disease and the National Institutes of Health sponsored a large multicenter clinical trial of pegylated interferon plus ribavirin in African Americans to establish an accurate estimate of the response rates in this group. The study also included basic research looking at the reasons for non-response among African Americans with hepatitis C.

The "Study of Viral Resistance to Antiviral Therapy of Chronic Hepatitis C" (Virahep-C) was conducted at eight clinical centers and a data-coordinating center. In addition, four ancillary studies were funded to focus on the basis for antiviral resistance. The main study enrolled 400 treatment-naïve patients (never been treated) with chronic genotype 1 HCV. Of the total, 200 patients were African American and 200 were Caucasian. All participants received a course of pegylated interferon alpha 2a (Pegasys) plus Copegus (ribavirin), and were followed for symptoms, treatment -related side effects, compliance, serum biochemical markers of liver disease, and HCV RNA (viral load) levels. Blood samples were taken at specified intervals to study immune function, interferon signaling, and genetic markers.

The results of the study found that the sustained virological response rates were lower in African Americans compared with whites (31% vs. 55%). There seemed to be a difference in the degree of viral suppression during the first 28 days of treatment that might explain the differences in treatment response. But even after factoring in these differences it is not completely clear why African Americans do not achieve comparable treatment results. The authors stated that more studies are needed.

IL28B

The reasons for the lower treatment response rates to older HCV therapies are not completely understood, but one known factor is a genetic variation of the IL28B gene. IL28B or interleukin 28B is part of our natural immune system that triggers our body to make more of a type of natural interferon called lambda interferon. The presence of a certain variation of IL28B called CC genotype indicates a better chance of producing more of a stronger immune response. In recent studies it has been found that people with hepatitis C genotype 1 who have naturally rid their bodies of the hepatitis C virus or who were successfully treated are more likely to have the CC genotype. African Americans in the studies were less likely to have the positive gene variation (cc genotype). This explains some of the differences, but more studies are need to completely understand the differences in HCV treatment response rates.

HCV Treatment Response

In the past, African Americans as a group did not respond as well to HCV medications, but with the approval of new drugs in 2013 to treat HCV, the cure rates are similar between African Americans and other races. The current standard of care for treating HCV is a combination of an HCV inhibitor (sofosbuvir or simeprevir) plus pegylated interferon plus ribavirin to treat HCV genotype 1 and 4. People with HCV genotype 2 and 3 are treated with sofsbuvir plus ribavirin (no interferon).

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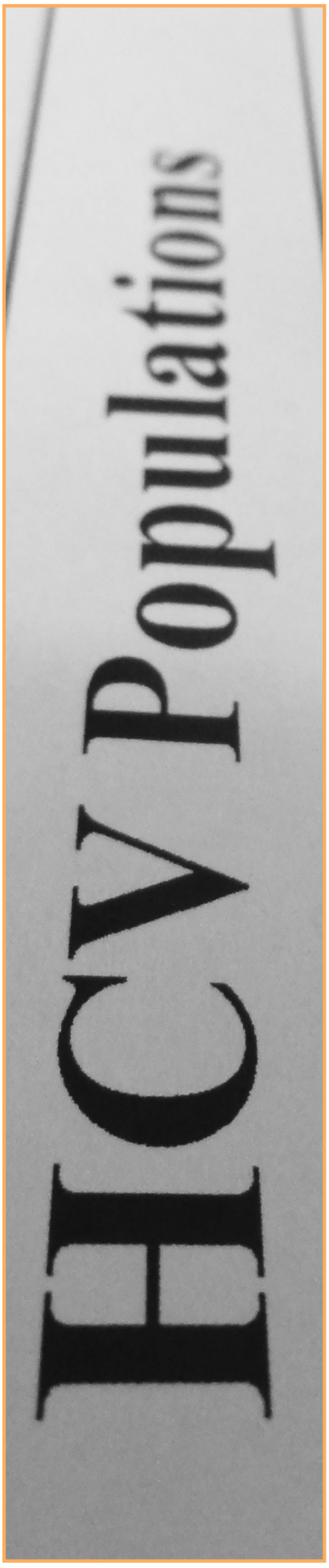
The Future

There are many studies being conducted with new drugs to treat hepatitis C. These studies are a combination of various HCV inhibitors (blocking HCV from replicating) that do not include interferon and/or ribavirin. These therapies will have higher cure rates and lower side effects. This will mean that most everyone will be able to tolerate therapy and be cured of hepatitis C including African Americans.



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