Epclusa Is a Good Hep C Treatment Option for Underserved Groups

Homeless people, incarcerated individuals and people with mental health conditions achieved a high cure rate.

August 30, 2020 By Liz Highleyman

The once-daily combination pill Epclusa led to a 98% cure rate, after excluding those lost to follow-up, in a study of nearly 2,000 people who were homeless, incarcerated or had mental health conditions, according to a report this week at the Digital International Liver Congress.

In order to successfully eliminate hepatitis C, it will be necessary to treat all segments of the population, including groups that have traditionally been considered difficult to treat. Easy-to-use regimens with a high cure rate are needed to treat these underserved groups. "Simplification of the treatment cascade and rapid treatment start is key to achiev[ing] this goal, even more so in the COVID-19 era," Lisa Barrett, MD, PhD, of Dalhousie University in Halifax, Canada, and colleagues noted as background.

Gilead Science's Epclusa (sofosbuvir/velpatasvir) is a one-pill, once-daily regimen taken for 12 weeks that can treat all genotypes of HCV without the need for pretreatment genotypic testing. It can be taken with or without food and has few interactions with other medications.

Barrett presented findings from a real-world study of the effectiveness of Epclusa as a simple regimen for a test-and-treat approach for vulnerable populations, including people with mental health conditions, people experiencing homelessness and incarcerated individuals.

The analysis included 1,888 adults with hepatitis C from 33 clinical cohorts in the United States, Australia, Canada and Europe who completed a 12-week course of Epclusa prior to February 2020. Participants could have any HCV genotype, could be new to treatment or treatment-experienced (but could not have previously used HCV NS5A inhibitors) and could have any stage of liver fibrosis up to and including compensated cirrhosis. People with more severe decompensated cirrhosis or liver cancer, those who were treated for more than 12 weeks and those who took Epclusa with ribavirin were excluded.

Three quarters were classified as having a mental health condition, with depression, anxiety and cognitive or psychiatric disorders being most common. About 8% were homeless and 28% were incarcerated; a majority of the homeless people and a quarter of the incarcerated people also had

mental health conditions. About half had a known history of injection drug use, including 20% who reported current active drug use. About a quarter were concurrently taking psychiatric medications.

About 70% of the participants overall were men, rising to about 90% in the homeless and incarcerated subgroups. About 43% had HCV genotype 1, 12% had genotype 2, 36% had genotype 3 and 6% had genotypes 4, 5 or 6, with some variation in distribution across the subgroups.

While a majority had absent to moderate liver fibrosis, 19% had already progressed to cirrhosis. About 12% had been previously treated for hep C.

Overall, 84.6% of the full study population achieved a sustained virological response (SVR), meaning continued undetectable HCV viral load 12 or more weeks after completing treatment, which is considered a cure.

The overall SVR rates were 83.1% for incarcerated people, 79.7% for homeless people and 85.5% for those with mental health conditions alone. Only 1.7% experienced virological treatment failure.

Among the 1,631 people with available data on treatment outcomes (dubbed the effectiveness population), the SVR rates were 98.9% for incarcerated people, 100% for homeless people and 97.6% for those with mental health conditions alone. Cure rates were high regardless of genotype, fibrosis stage or active drug use.

For the subset of participants with available information on treatment adherence, 2.3% had less than 80% adherence and 4.0% had less than 90% adherence—rising to 10.1% and 16.8%, respectively, in the homeless group—but nonetheless all of them were cured.

Another 257 people (about 14% of the total study population) did not have either documented SVR or virological treatment failure, mostly because of loss to follow-up (224 people). Twenty-seven people stopped treatment early, eight were reinfected after being cured, six were considered nonadherent to treatment, four died during follow-up and 33 had unknown reasons for not achieving SVR.

Incarcerated people were more likely to be lost to follow-up, people with mental health conditions were more likely to discontinue treatment and homeless people were more likely to be reinfected.

“This large, diverse real-world data set shows high SVR rates with sofosbuvir/velpatasvir for 12 weeks across key patient populations traditionally considered difficult to engage in care,” the researchers concluded. “Overall, low rates of noncompliance and reinfection were seen in this challenging patient population.”

Further, they noted, this regimen allows for an easily implemented test-and-treat strategy and decentralization of care, as supported by liver disease associations from the United States, Latin America, Europe and Asia in a global call to action to simplify treatment in an effort to eliminate hepatitis C as a public health threat.

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