Sovaldi-Based Hep C Regimens Less Successful in Real World

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The real-world cure rates offered by Sovaldi (sofosbuvir)–based hepatitis C virus (HCV) regimens have not been as good as those seen in clinical trials, at least among a group of veterans with genotypes 1 or 2, Healio reports. Publishing their findings in Alimentary Pharmacology & Therapeutics, researchers analyzed data from the Veterans Affairs Clinical Case Registry for HCV on 4,026 vets treated for hep C with 12-week Sovaldi–based regimens.

A total of 3,203 of the vets had genotype 1 and 823 had genotype 2.

Gilead Sciences' Harvoni (ledipasvir/sofosbuvir) has superseded Sovaldi–based regimens (Sovaldi is also a Gilead drug) as the treatment of choice for those with genotype 1. So this study's findings may not be applicable to the current realities of hep C treatment among that group, especially since this study looked in part at the results of regimens including interferon, which causes flu-like side effects. Interferon has largely been edged out of the hep C arsenal.

However, 12 weeks of Sovaldi plus ribavirin is still the top-recommended regimen for treatment-naive people with genotype 2, which makes this study more relevant to that population's current concerns.

The rates of those with genotype 1 who achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure) for the respective regimens were: Sovaldi plus interferon and ribavirin, 66.8 percent; Sovaldi and Janssen's Olysio (simeprevir), 75.3 percent; Sovaldi and Olysio plus ribavirin, 79 percent.

Seventy-nine percent of genotype 2s who took Sovaldi and ribavirin were cured.

A significant proportion of the veterans discontinued care. Because these individuals were still factored into the calculations for the cure rates, their decision to stop therapy was a major factor contributing to the depressed SVR rates when compared with the rates seen in clinical trials.

Individuals with genotype 1 were 36 percent less likely to achieve a cure if they had a body mass index (BMI) of at least 30, 49 percent less likely if they had a history of decompensated liver disease, 42 percent less likely if they were treatment experienced, 56 percent less likely if they had an APRI score greater than 2 (indicating higher liver damage), and 50 percent less likely if

they took Sovaldi plus interferon and ribavirin compared with taking Sovaldi and Olysio. Cure rates were not apparently affected by age, sex, race or ethnicity, diabetes status, or hep C genotype subtype. Adding ribavirin to the Sovaldi and Olysio regimen did not improve the chance of cure.

Those with genotype 2 were 45 percent less likely to achieve an SVR if they were treatment experienced and 61 percent less likely with an APRI score greater than 2.

The researchers theorize that the depressed SVR rates may be explained in part by differences between the population of veterans treated and the participants admitted to clinical trials of hep C therapies. Those trials had certain stringent entry criteria that ultimately may have excluded individuals who had a lesser chance of a cure. Other factors, such as clinical practice patterns, patient motivation, the knowledge and resources of clinicians, and other services the clinics may offer, could also help explain the lowered cure rates.

To read the Healio article, click here.

To read the study abstract, click here.

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