Evaluation of sofosbuvir-based regimens for the treatment of hepatitis C in patients with decompensated cirrhosis


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Objective: To assess the effectiveness and safety of sofosbuvir (SOF)-based regimens for treatment of HCV in patients with decompensated cirrhosis within the Veteran Affairs (VA) healthcare system.

Background: It is estimated that 2.7-3.9 million Americans are infected with chronic Hepatitis C virus (HCV). Prior to the introduction of direct acting antivirals, patients with decompensated cirrhosis had limited treatment options. The AASLD-IDSA guidelines recommend three different SOF-based regimens for treatment of HCV in patients with decompensated cirrhosis. However, there is still limited real-world data evaluating the use of these medications in this population.

Methods: This study was a retrospective chart review evaluating VA patients with chronic HCV and decompensated cirrhosis who had completed and received HCV treatment with a SOF-based regimen through the VA. Patients with decompensated liver disease were included in the study if they initiated HCV treatment with a SOF-based regimen between October 10, 2014 and December 31, 2016 and were expected to complete treatment by December 31, 2016. All patients who filled prescriptions for SOF or ledipasvir(LDV)/SOF during this period were extracted from the National VA Corporate Data Warehouse. Patients with decompensated cirrhosis were identified using a drug flag for rifaximin, which has specific criteria for use within the VA system. These patients were randomized and a convenience sample of 110 patients was reviewed for presence of decompensated cirrhosis through manual chart review. Patients were determined to have decompensated cirrhosis if they had a history of hepatic encephalopathy, ascites, spontaneous bacterial peritonitis, or bleeding esophageal varices. Effectiveness was determined using rates of sustained virologic response at least 12 weeks after completion of therapy (SVR12). SVR12 was also assessed among subgroups based on prior treatment experience and age. Safety was assessed using rates of adverse effects and hospital admissions during therapy. Descriptive statistics were used to assess effectiveness and safety data.

Results: Four-hundred and eight patients filled SOF or LDV/SOF between October 10, 2014 and December 31, 2016 and used rifaximin at any time. After manual review of the convenience sample, 78 patients met inclusion and exclusion criteria. Seventy-three percent of patients were infected with HCV genotype 1 and the majority were treated with a LDV/SOF regimen. Almost 76% of treatment-naïve and 81% of treatment-experienced patients achieved SVR12. While 43% of patients experienced an adverse effect, they were generally mild and often transient. The most common adverse effects were fatigue, headache, and nausea. Eleven patients were hospitalized during therapy for HCV-related complications; none were due to drug-related effects.

Conclusions: SOF-based regimens appear to be well-tolerated in patients with decompensated cirrhosis and have similar effectiveness in real-world use as was seen in randomized controlled trials.