The Efficacy and Safety of Sofosbuvir/Ledipasvir Therapy in Patients on Long-term Hemodialysis with Hepatitis C Virus Infection

Sir,

The Hepatitis C virus (HCV) infection is a serious health problem in hemodialysis (HD) patients worldwide. Among these patients, the prognosis of patients with HCV-infection is significantly worse than in patients without HCV infection; the survival of renal allograft is also worsened in HCV-infected than in non HCV-infected patients.[1] The Kidney Disease Improvement Global Outcome guidelines recommend anti-HCV therapy for HD patients with HCV infection on renal transplant waiting list.[2] The treatment of HCV- infection has progressed markedly over the last two decades, but HCV-infected patients on long-term HD rarely receive antiviral treatment because of adverse events of interferon (IFN)-based therapy. Although some studies highlight the effectiveness of more recent IFN-free anti-HCV therapy in patients with end-stage renal disease (ESRD), without relevant adverse events, there are limited data on the experience with new direct-acting antiviral drugs in patients on long-term HD.[3] Since 2014, in the European Union, Sofosbuvir (SOF) 400 mg/Ledipasvir (LDV) 90 mg (Harvoni®) is licensed for chronic HCV infection therapy. Approximately 80% of SOF is excreted by kidneys, whereas 15% is excreted in feces. Biliary excretion is the major route of elimination of unchanged LDV with renal excretion being a minor pathway (approximately 1%). Concerns have been raised because of the higher concentrations of SOF and its metabolites in patients with ESRD on dialysis as compared with patients with normal renal function. According to the latest EASL Guidelines (September 2016), no dose adjustment of SOF/LDV is required for patients with mild or moderate renal impairment (estimated glomerular filtration rate [GFR] >30 ml/min/1.73 m2), and a full-dose SOF is recommended in patients with stage 5 chronic kidney disease CKD on dialysis; however, the safety has not been assessed in patients with stage 4 or 5 CKD not on dialysis.[4] In the experience of Saxena *et al*., a progressive deterioration of renal function and renal symptoms was reported in patients with eGFR ≤45 ml/min/1.73 m2 receiving an SOF-based regimen, although efficacy was comparable to that observed in patients without renal impairment.[5] We report our experience in a patient on long-term HD with HCV infection. A 58-year-old male, born in Sicily (Southern Italy), was receiving HD. From 1989, he had been suffering from chronic kidney disease due to congenital renal hypoplasia. He was infected with HCV of genotype 1b. Blood transfusions, carried out before 1990 (beginning of the routine screening for HCV in Italy), were probably the transmission source of HCV-infection. He had not received IFN-based therapy. He was suffering from hypertensive heart disease and goiter; underwent thyroidectomy. He was taking doxazosin, metoprolol, irbesartan, calcitriol, allopurinol, acetylsalicylic acid, and levothyroxine. In 2016, the patient started the workup for renal transplant. Laboratory investigations highlighted albumin 3.2 g/dL, aspartate aminotransferase 18 U/L, alanine aminotransferase 17 U/L, gamma glutamyl transferase 16 U/L, total bilirubin 0.4 mg/dL, hemoglobin 12.7 g/dL, platelet count 220x103/μL, and prothrombin time International normalizated ratio 0.94%. The Abdomen Computed Tomography showed a liver with slight increase in volume and smooth edge without focal lesions or dilation of the biliary tract. He was treated with SOF/LDV 1 tablet/day for 12 weeks. At the baseline (April 2016), the viral load was 1,297,000 IU/ml. The patient had a sustained virological response at 12 and 24 weeks after the treatment. At follow-up (January 2017), the HCV-RNA was negative. In this period, he did not suffer from any of the most common adverse events of SOF/LDV treatment (fatigue and headache), and we did not observe any abnormalities of the common laboratory parameters. In our experience, we report the efficacy and the safety of SOF/LDV therapy in a patient on long-term HD with HCV-infection.

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Conflicts of interest

There are no conflicts of interest.

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