Safety and efficacy of sofosbuvir plus simeprevir in a spanish cohort of 622 cirrhotic patients infected with genotypes 1 or 4

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Background and Aims: The combination of Sofosbuvir (SOF), apolymerase inhibitor, plus Simeprevir (SMV), a protease inhibitor(PI), with or without ribavirin (RBV), has shown a good efficacy and safety profile in compensated cirrhotic patients infected with thehepatitis C virus (HCV) genotype (GT) 1 or 4. To date, there is no available data regarding the efficacy of this combination in real-life cirrhotic patients in Spain. The aim of this multicentric study was to assess the Spanish clinical experience using SOF/SMV (±RBV) in a large cohort of real-life compensated cirrhotic patients.

Methods: Retrospective analysis of data from GT1 and GT4 infected cirrhotic patients treated with this oral antiviral combination.

Results: Six-hundred and 22 cirrhotic patients were included. Cirrhosis was defined according to clinical, histological, ultrasonographic or elastographic criteria. The majority of patients were male (62%) and the median age was 59 years (23–80). Patients were infected with GT1a (20%), 1b (67%) or 4 (10%). The median transient elastographic measurement was 21.8 KPa (P2516.6; P7533.3); the MELD score was 8(5–26) and the majority of patients(73.5%) were Child-Pugh A at baseline. Up to 58.5% of patients had previously failed to antiviral therapies; importantly 17% of them had already received a PI-based regimen. Baseline median ALT was 69(5–513) and viral load (HCV-RNA) was 6.06 log10IU/mL (1.28–8.29). The majority of patients (78%) were treated for 12 weeks and 62% of the cohort received RBV. Fourteen patients are still on treatment; 8patients had to prematurely discontinue therapy (1 due to an allergic reaction, 1 committed suicide, 1 had hepatocellular carcinoma progression, 2 patients presented liver decompensation and in 3cases was unknown). At the end of treatment (EOT), all patients had undetectable serum HCV-RNA. The rates of sustained virological response (SVR) 4 and 12 weeks after therapy were 95.5% (485/505)and 88.5% (415/469), respectively. SVR rate was similar among patients, regardless of the use or not of RBV. There were 54 (8.7%) reported virological failures. Safety profile will be reported.

Conclusions: The combination of SOF/SMV (with or without RBV) isvery effective in cirrhotic patients infected with GT1 and 4 in Spain.The high prevalence of G1b infection may explain the higher efficacycompared with other real-life cohorts.