

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

Z. Mariño¹, J.M. Pascasio², G. Sánchez-Antolin³, C. Baliellas⁴, M. Prieto⁵, J.M. Moreno⁶, J.A. Carrión⁷, I. Fernández⁸, A. Gomez⁹, J.L. Montero¹⁰, A. Castro¹¹, S. Pascual¹², J. Cabezas¹³, A. Arencibia C. Del¹⁴, J.L. Calleja¹⁵, J.J. Sanchez-Ruano¹⁶, L. Castells¹⁷, A. Albillos¹⁸, M. Romero¹⁹, J. García-Samaniego²⁰, I. Narváez²¹, T. Serrano²², A. Giraldez²³, X. Xiol²⁴, V. Hontangas⁵, V. Cuervas-Mons²⁵, J. Crespo¹³, X. Forns¹, on behalf of Hepa-C Registry Group.

¹ Hospital Clinic, IDIBAPS-CIBERehd, Barcelona; ² Hospital Virgen del Rocío, Sevilla; ³ Hospital Río Hortega, Valladolid; ⁴ Hospital Bellvitge-IDIBELL, Barcelona; ⁵ Hospital Universitario de la Fe, Valencia; ⁶ Hospital de Albacete, Albacete; ⁷ Hospital del Mar, Barcelona; ⁸ Hospital Universitario 12 de Octubre, Madrid; ⁹ Hospital Universitario de Donostia, Donostia; ¹⁰ Hospital Universitario Reina Sofía, Córdoba; ¹¹ Hospital Universitario A Coruña, A Coruña; ¹² Hospital General, Alicante; ¹³ Hospital Marqués de Valdecilla, Santander; ¹⁴ Hospital Nuestra Señora de la Candelaria, Canarias; ¹⁵ Hospital Puerta del Hierro, Madrid; ¹⁶ Hospital de Toledo, Toledo; ¹⁷ Hospital Vall d'Hebron, Barcelona; ¹⁸ Hospital Ramón y Cajal, Madrid; ¹⁹ Hospital Virgen de Valme, Sevilla; ²⁰ Hospital La Paz, Madrid; ²¹ Hospital Infanta Cristina, Badajoz; ²² Hospital Clínico, Zaragoza; ²³ Hospital Virgen del Rocío, Sevilla; ²⁴ Hospital de Bellvitge-IDIBELL, Barcelona; ²⁵ Hospital Puerta de Hierro, Madrid, Spain

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 the hepatitis 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; 8 patients 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 3 cases 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) is very effective in cirrhotic patients infected with GT1 and 4 in Spain. The high prevalence of G1b infection may explain the higher efficacy compared with other real-life cohorts.