

High efficacy and tolerability of hepatitis C genotype 2 treatment with direct-acting antivirals in real world: analysis of the Hepa-C Registry

E.B. Aranda¹, Z. Mariño², S. Calvo³, J.A. Carrión⁴, I. Fernández⁵, J. García-Samaniego⁶, C. Baliellas⁷, J.M. Pascasio⁸, A. Albillos⁹, C.F. Carrillo¹⁰, A.C. Iglesias¹¹, J.M.M. Planas¹², C.P. Giner¹³, J.J.M. Palomares¹⁴, J. Llaneras¹⁵, J. Arenas¹⁶, M. Fernández-Bermejo¹⁷, C. Fernández¹⁸, R.M.G. Lopez¹⁹, P.B. García²⁰, M. Romero-Gómez²¹, F. Sáez-Royuela¹ and Hepa-C Registry.

¹ Hospital Universitario de Burgos, Burgos; ² Hospital Clínic, IDIBAPS, CIBERehd, Barcelona; ³ Fundación Burgos por la Investigación de la Salud, Hospital Universitario de Burgos, Burgos; ⁴ Hospital del Mar, Barcelona; ⁵ Hospital Universitario 12 de Octubre; ⁶ Hospital Carlos III, CIBERehd, Madrid; ⁷ Hospital Universitari de Bellvitge-IDIBELL, Barcelona; ⁸ Hospital Universitario Virgen del Rocío, Sevilla; ⁹ Hospital Universitario Ramón y Cajal, Madrid; ¹⁰ Hospital Universitario Puerta de Hierro. IDIPHIM, CIBERehd, Majadahonda, Madrid; ¹¹ Hospital Universitario A Coruña, A Coruña; ¹² Complejo Hospitalario Universitario Albacete, Albacete; ¹³ Hospital General de Castellón, Castellón; ¹⁴ Hospital General de Segovia, Segovia; ¹⁵ Hospital Vall d' Hebron, CIBERehd, Barcelona; ¹⁶ Hospital Universitario Donostia, San Sebastián; ¹⁷ Hospital San Pedro de Alcántara, Cáceres; ¹⁸ Hospital Fundación Alcorcón, Madrid; ¹⁹ Hospital de Cabueñes, Gijón; ²⁰ Hospital General de Alicante, Alicante; ²¹ HUV Macarena-Rocío, Sevilla, Spain

Background and Aims: Direct-acting antivirals (DAA) have improved global sustained virological response (SVR) above 90%. Real world treatments in hepatitis C genotype 2 (G2) patients with DAA have been little studied in Spain and other European countries, with high SVR in Asian countries. The main aim was to evaluate the efficacy and tolerability of DAA in hepatitis C G2 patients in real world. The secondary aim was to describe the clinical characteristics and the pattern of treatments used in these patients.

Methods: Multicenter, descriptive and observational study of monoinfected hepatitis C G2 patients treated with DAA included in the Spanish registry Hepa-C (directed by the Spanish Association for the Study of the Liver). Liver transplant recipients were excluded. Demographic, clinical and virological variables, treatment and adverse events (AEs) were analysed.

Results: A total of 102 G2 patients under DAA treatment were registered, 73 of them have finished treatment, preliminary results are presented. Characteristics: 51% men, mean age 60 years (15 – 86), BMI 27,3 (16,9 – 43,6) Kg/m², platelet count 132×10^3 /mm³ (131 – 416), ALT 60 UI/mL (9 – 405), RNA-HCV 5,9 log₁₀ IU/mL (3,5 – 7,7). Mean fibrosis measured by transient elastography was 11,2 KPa (3,7 – 54,3). Cirrhosis was found in 56% (41/73); 90% (37/41) Child A, 10% (4/73) Child B. A 67% (49/73) of patients were naïve. DAA combinations used were sofosbuvir (SOF) + RBV: 92% (67/73) and SOF + daclatasvir (DCV) without RBV: 8% (6/73). In SOF + RBV, treatment was extended to 24 weeks in 78% (52/67) and in 50% (3/6) in SOF + DCV treated patients. The global SVR was 96% (70/73); SOF + RBV: 96% (64/67) and SOF + DCV: 100% (6/6). One of the non-SVR patients had cirrhosis and all of them were naïve; they had a statistically significant lower RNA-HCV and they were younger than SVR

patients. AEs were described in 42% (31/73), the most frequent AE was anaemia (16/73, 22%), with SOF + RBV in 15 cases and 1 with SOF + DCV. Erythropoietin (EPO) was required in 2 patients and 4 need a blood transfusion (all in SOF + RBV group). Two patients had hepatic decompensation. There were not treatment related deaths. Any treatment was stopped because of AEs.

Conclusions: SVR rates in hepatitis C G2 patients are >95% with the two of the studied DAA combinations, and similar to real world data published in Asian countries. RBV was related to an increase rate of AEs, especially anaemia that in some occasion required EPO or blood transfusion. In the ILC we will present actualized data with an enlarged sample