

J. González-García¹, J. Berenguer², M.J. Vivancos³, J. Navarro⁴, M.J. Téllez⁵, J.M. Guardiola⁶, J.A. Iribarren⁷, A. Rivero-Román⁸, M. Márquez⁹, A. Artero¹⁰, L. Morano¹¹, I. Santos¹², J. Moreno¹³, M.C. Fariñas¹⁴, M.J. Galindo¹⁵, A. Hernando¹⁶, M. Montero¹⁷, C. Cifuentes¹⁸, P. Domingo¹⁹, J. Sanz²⁰, L. Pérez-Latorre¹, V. Hontañón², L. Domínguez¹⁶, O.L. Ferrero²¹, B. De la Fuente²², C. Rodríguez²³, S. Reus²⁴, J. Hernández-Quero²⁵, G. Gaspar²⁶, L. Pérez-Martínez²⁷, C. García²⁸, L. Force²⁹, S. Veloso³⁰, J.E. Losa³¹, J. Vilaró³², E. Bernal³³, S. Arponen³⁴, A.J. Ortí³⁵, Á. Chocarro³⁶, R. Teira³⁷, G. Alonso³⁸, R. Silvarinho³⁹, A. Vegas⁴⁰, P. Geijo⁴¹, J. Bisbe⁴², I. Jarrín⁴³, H. Esteban⁴⁴, and GeSIDA 8514 Study Group

¹Hospital Universitario La Paz/IdiPAZ, Madrid. ²Hospital General Universitario Gregorio Marañón, Madrid. ³Hospital Universitario Ramón y Cajal, Madrid. ⁴Hospital Vall d'Hebrón, Barcelona. ⁵Hospital Clínico de San Carlos, Madrid. ⁶Hospital Santa Creu y San Pau, Barcelona. ⁷Hospital Donostia, San Sebastián. ⁸Hospital Universitario Reina Sofía, Córdoba. ⁹Hospital Virgen de la Victoria, Málaga. ¹⁰Hospital Doctor Peset, Valencia. ¹¹Hospital Universitario Álvaro Cunqueiro, Vigo. ¹²Hospital Universitario de la Princesa, Madrid. ¹³Hospital Miguel Servet, Zaragoza. ¹⁴Hospital Marqués de Valdecilla, Santander. ¹⁵Hospital Clínico de Valencia, Valencia. ¹⁶Hospital Universitario 12 de Octubre, Madrid. ¹⁷Hospital La Fe, Valencia. ¹⁸Hospital Son Llàtzer, Palma de Mallorca. ¹⁹Hospital Universitario Arnau de Vilanova, Lleida. ²⁰Hospital Universitario Príncipe de Asturias, Alcalá de Henares. ²¹Hospital Universitario de Basurto, Bilbao. ²²Hospital de Cabueñes, Gijón. ²³Centro Sanitario Sandoval, Madrid. ²⁴Hospital General de Alicante, Alicante. ²⁵Hospital Clínico San Cecilio, Granada. ²⁶Hospital Universitario de Getafe, Getafe. ²⁷Hospital de la Rioja, Logroño. ²⁸Hospital Virgen de las Nieves, Granada. ²⁹Hospital de Mataró, Mataró. ³⁰Hospital Joan XXIII, Tarragona. ³¹Fundación Hospital Alcorcón, Alcorcón. ³²Hospital Universitari de Vic, Vic. ³³Hospital Reina Sofía, Murcia. ³⁴Hospital Universitario de Alcalá Torrejón, Torrejón de Ardoz. ³⁵Hospital Virgen de la Cinta, Tortosa. ³⁶Hospital Virgen de la Concha, Zamora. ³⁷Hospital de Sierrallana, Torrelavega. ³⁸Hospital Rafael Méndez, Lorca. ³⁹Hospital San Eloy, Baracaldo. ⁴⁰Hospital Infanta Elena, Valdemoro. ⁴¹Hospital Virgen de la Luz, Cuenca. ⁴²Fundació Hospital Sant Jaume, Olot. ⁴³Instituto de Salud Carlos III, Madrid. ⁴⁴Fundación SEIMC/GESIDA, Madrid, Spain

Background

- The benefits of eradicating HCV among coinfected individuals regarding reduced liver-related and non-liver-related morbidity and mortality are well-known.¹
- However, in patients with cirrhosis in whom HCV has been eradicated, there persists a residual risk for liver-related events, especially hepatocellular carcinoma.²
- Surveillance for hepatocellular carcinoma with liver imaging should be pursued twice annually for an indefinite duration in all patients with stage 3 fibrosis or liver cirrhosis post-SVR.³

1. Berenguer J, et al. Hepatology 2017; 66(2): 344-56.
2. van der Meer AJ, et al. J Hepatol 2017; 66(3): 485-93.
3. EASL. J Hepatol 2017; 66(1): 153-194

Aims

- To assess the prevalence of HIV/HCV-coinfection in Spain in 2016
- To define the clinical characteristics of HIV/HCV-coinfected patients with particular attention to assess the burden of HCV-cirrhosis among those who achieved SVR after anti-HCV therapy

Methods

Design	• Nationwide cross-sectional study
Study period	• October-November 2016
Reference population	• All HIV+ patients in active follow-up in the participating centers*
Sample size estimation	• Confidence level 95% • Design effect 1.0 • Accuracy of 2.0%
Patient selection	• Number of patients from each hospital determined by proportional allocation • Patients were selected using simple random sampling
Data recording	• Online CRF

*Active follow-up = at least 1 visit in the previous 12 months

Definition of liver cirrhosis

- The presence of liver cirrhosis was investigated in all patients, as was the method of diagnosis, namely, liver biopsy, transient elastography (liver stiffness > 12.5 kPa), or clinical/biological findings.
- Patients with prior or current episodes of ascites, hepatic encephalopathy, or variceal bleeding were considered to have decompensated liver disease.
- In patients with cirrhosis, current Child-Pugh and model for end-stage liver disease (MELD) scores were recorded.
- We also recorded whether patients had been diagnosed with hepatocellular carcinoma and whether they had undergone liver transplantation.

Centers, Population, Sample Size

Centers	• 43 centers
Reference population	• 38,904 HIV+ patients
Sample Size	• 1,588 HIV+ patients

Data recording Online CRF

Prevalence of HCV Ab+ and HCV-RNA+

HCV serology known in 1,585 of 1,588 patients (99.8%)

Characteristics of patients according to HCV serology

	HCV-Ab+ (N = 548)	HCV-Ab- (N = 1037)	P
Male sex, n (%)	415 (75.7)	805 (77.6)	.39
Age years, mean (SD) ²	51 (7)	47 (12)	<.001
IDU as HIV transmission category, n (%)	417 (76.1)	53 (5.1)	<.001
CDC clinical category C, n (%)	166 (30.3)	236 (22.8)	.001
cART, n (%)	538 (98.2)	994 (95.8)	.014
Type of cART regimen, n (%)			
2 NRTI + 1 NNRTI	136 (25.2)	376 (37.8)	
2 NRTI + 1 PI	74 (13.7)	118 (11.9)	
2 NRTI + 1 integrase inhibitor	183 (33.9)	312 (31.4)	<.001
PI-based monotherapy	36 (6.7)	49 (4.9)	
PI-based bitherapy	53 (9.8)	56 (5.6)	
Other	57 (10.6)	83 (8.3)	
HIV-RNA copies/ml, n (%), patients on cART			
<50	488 (90.7)	924 (93.0)	
50-200	23 (4.3)	30 (3.0)	.28
>200	27 (5.0)	40 (4.0)	
CD4+ – T cells/μL, median (IQR), patients on cART	659 (431-886)	678 (495-910)	.039

HCV-RNA results & HCV genotypes

Fibrosis staging in HCV-RNA+ patients

Patients with TE = 150 (80.6%) TE value, median (IQR) = 6.6 (5.4 - 9.1)

Patients with FIB-4 = 185 (99.5%) FIB-4 value, median (IQR) = 1.5 (1.1 - 2.2)

Cirrhosis among HIV-infected patients

- Presence of cirrhosis
 - 120/1588 (7.6%) patients overall
 - 28/186 (15.0%) patients with active HCV infection
 - 92/292 (31.5%) patients who cleared HCV after SVR
- Assuming 130,000-160,000 people living with HIV in Spain
 - There are between 9,120 and 12,160 HIV-infected individuals with HCV-related cirrhosis

Prevalence and characteristics of cirrhosis among HCV-RNA+ patients and HCV-RNA+ patients after SVR

	HCV-RNA+ (N = 186)	HCV-RNA+ after SVR (N = 292)	P
Liver cirrhosis, n (%)	28 (15.0)	92 (31.5)	<.001
Decompensated cirrhosis, n (%)	4 (14.3)	8 (8.7)	.39
Hepatocellular carcinoma, n (%)	1 (3.6)	1 (1.1)	.37
Serum albumin, median (IQR)	4.0 (3.5 – 4.6)	4.4 (4.0 – 4.7)	.046
Patients with FIB-4, n (%)	28 (100.0)	92 (100.0)	
FIB-4 value - Median (IQR)	2.8 (1.6 – 5.1)	2.0 (1.4 – 3.2)	.047
Patients with TE, n (%)	27 (96.4)	84 (91.3)	
Last TE value – kPa, median (IQR)	10.9 (3.2 – 25.4)	14.7 (7.7 – 34.3)	.29

Conclusions

- With universal access to DAA-based therapy and continued efforts in prevention and screening, it will be possible to eliminate active HCV among HIV-infected individuals in Spain in the short term.
- The burden of HCV-related cirrhosis, however, will continue to be significant among HIV-infected individuals.

Funding

- Grants Ref# RD16/0025/0017 and RD16/0025/0018 from the Spanish AIDS Research Network that is included in the Spanish I+D+i Plan and is co-financed by ISCIII-Subdirección General de Evaluación and European Funding for Regional Development (FEDER).
- Grant Ref# GLD14-00279 from the GILEAD Fellowship Programme (Spain)

GeSIDA 8514 Study Group

Principal Investigators: J Berenguer and J González
Study Coordinator: H Esteban - **Statistician:** I Jarrin

Hospital Gregorio Marañón, Madrid: L Pérez-Latorre, P Miralles, JC López, F Parras, B Padilla, T Aldámiz, A Carrero, C Díez, F Tejerina, and J Berenguer. Hospital La Paz, Madrid: V Hontañón, MJ Núñez, R Mico, F Arnalich, JI Arribas, JI Bernardino, MI Martín-Carbonero, R Montejano, MI Montes, V Moreno, I Pérez-Valero, C Navarro, E Valencia, and J González-García. Hospital Ramón y Cajal, Madrid: MJ Vivancos, S Moreno, A Moreno, JL Casado, MJ Pérez-Ellias, and C Quereda. Hospital 12 de Octubre, Madrid: L Domínguez, A Hernando, D Bisbal, M De Lagarde, M Matarranz, Rafael Rubio, and F Pulido. Hospital Vall d'Hebrón, Barcelona: J Navarro, A Torrella, and N Ramos. Hospital Clínico San Carlos, Madrid: M Rodrigo, V Estrada, J Vargas, and MJ Téllez. Hospital Santa Creu i Sant Pau, Barcelona: J Muñoz, M Gutiérrez, G Mateo, and JM Guardiola. Hospital Donostia, San Sebastián: M Ibarburen, MP Carmona, F Rodríguez-Aranda, MA Goenaga, H Azkune, MA Von Wichmann, and JA Iribarren. Hospital Reina Sofía, Córdoba: T Brieva, A Camacho, IM Machuca, A Rivero-Juárez, and A Rivero-Román. Hospital Virgen de la Victoria, Málaga: J Ruiz, E Nuño, R Palacios, J Santos, and M Márquez. Hospital Doctor Peset, Valencia: J Carmona, and A Artero. Hospital Universitario Álvaro Cunqueiro, Vigo: L Morano, and M Crespo. Hospital de la Princesa, Madrid: L García, S Otero, J Sanz, and I Santos. Hospital Miguel Servet, Zaragoza: J Moreno, and P Arazo. Hospital Marques de Valdecilla, Santander: C Armiñanzas, S Echevarría, M Gutiérrez-Cuadra, and MC Fariñas. Hospital Clínico de Valencia, Valencia: A Ferrer, and MJ Galindo. Hospital La Fe, Valencia: M, Montero, M Tasis, S Cuellar, E Calabuig, M Blanes, J Fernández, J López-Aldague, and M Salaver. Hospital Son Llàtzer, Palma de Mallorca: C Cifuentes. Hospitales Universitarios Arnau de Vilanova y Santa Maria, Lleida: P Domingo. Hospital Principe de Asturias, Alcalá de Henares: I de Miguel, A Aranz, E Casas, and J Sanz. Hospital Universitario Basurto, Bilbao: OL Ferrero, S Ibarra, I López, M de la Peña, Z Zubero, J Baraia, and J Muñoz. Hospital de Cabueñes, Gijón: M Campoamor, M Tolo, and B de la Fuente. Centro Sanitario Sandoval, Madrid: C Rodríguez, T Puerta, M Raposo, M Vera, and J Del Romero. Hospital General de Alicante, Alicante: S Reus, L Giner, E Merino, V Bots, D Torriús, I Portilla, M Pampliega, M Díez, I Egea, and J Portilla. Complejo Hospitalario Universitario de Granada, Granada: D Vinuesa, L Muñoz, and J Hernández-Quero. Hospital Universitario de Getafe, Getafe: G Gaspar. Hospital San Pedro-CIBIR, Logroño: L García, L Pérez, and JA Otero. Hospital Virgen de las Nieves, Granada: C García. Hospital de Mataró, Mataró: L Force, and P Barriola. Hospital Universitari de Tarragona Joan XXIII, Tarragona: S Veloso, J Peraire, C Viladés, M Vargas, A Castellano, and F Vidal. Hospital Fundación de Alcorcón, Alcorcón: M Velasco, L Moreno, R Hervás, and JE Losa. Hospital Universitari de Vic, Vic: J Vilaró. Hospital Reina Sofía, Murcia: A Cano, A Alcaráz, A Muñoz, and E Bernal. Hospital Universitario de Torrejón: Torrejón de Ardoz: A Gimeno, C Montero, and S Arponen. Hospital Virgen de la Cinta, Tortosa: AJ Ortí, E Chamorro, and C Escrig. Hospital Virgen de la Concha, Zamora: A Chocarro. Hospital de Sierrallana, Torrelavega: R Teira. Hospital Rafael Méndez, Lorca: G Alonso, C Toledo, AI Peláez, G Lara, I Fernández, and MC Esteban. Hospital San Eloy-OSI, Baracaldo: R Silvarinho. Hospital Infanta Elena, Valdemoro: A Vegas. Hospital Virgen de la Luz, Cuenca: P Geijo. Hospital d'Olot i Comarcal de la Garrotxa, Olot: J Bisbe. Instituto de Salud Carlos III, Madrid: I Jarrin.