

ADVANCES IN CHRONIC HEPATITIS C: MANAGEMENT AND TREATMENT

INDEPENDENT REPORTING ON AASLD 2016

COMPREHENSIVE EXPERT REVIEW AND DISCUSSION OF KEY PRESENTATIONS

AN INDEPENDENT CME ACTIVITY JOINTLY PROVIDED BY POSTGRADUATE INSTITUTE FOR MEDICINE AND VIRAL, INC.
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Real-World Outcomes with New HCV Antivirals in HIV/HCV-Coinfected Subjects: Madrid Coinfection Registry (Madrid-CoRE) Findings

J. Berenguer, J. Gonzalez-García, M. Montes, Gil-Martin, E. Cruz-Martos, M. Calvo, M. Alcaraz,
L. Dominguez-Dominguez, T. Aldámiz-Echevarría

Abstract 78

Madrid-CoRe (Madrid Coinfection Registry): Baseline Characteristics

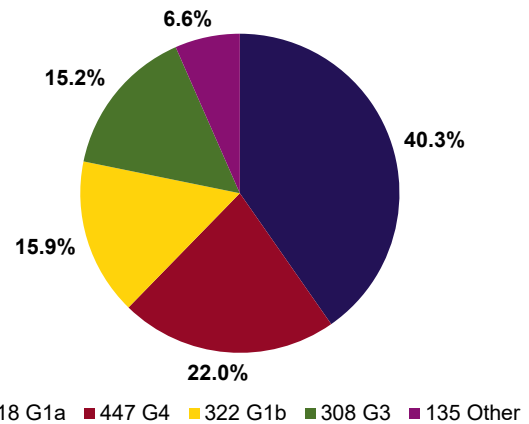
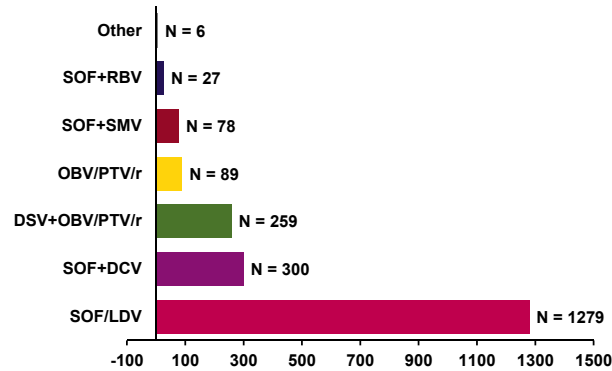
Variable	N = 2030
Age years – median (IQR)	50 (47 – 54)
Male – n (%)	1591 (78.4)
CD4+ T cells/ μ L – median (IQR)	570 (356 – 785)
cART – n (%)	1930 (95.1)
Liver disease severity	
No cirrhosis – n (%)	1125 (55.4)
Compensated cirrhosis – n (%)	754 (37.1)
Decompensated cirrhosis – n (%)	146 (7.2)
Unknown – n (%)	5 (0.3)
History of hepatocellular carcinoma – n (%)	15 (0.7)
Liver transplantation – n (%)	17 (0.8)
Liver transplantation waiting list – n (%)	7 (0.3)
Severe extrahepatic manifestations – n (%)	143 (7.0)
Anti-HCV – naïve – n (%)	1256 (61.9)
Liver stiffness kPa – median (IQR)	11.4 (8.1 – 20.2)

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HCV Genotypes and DAA Combinations

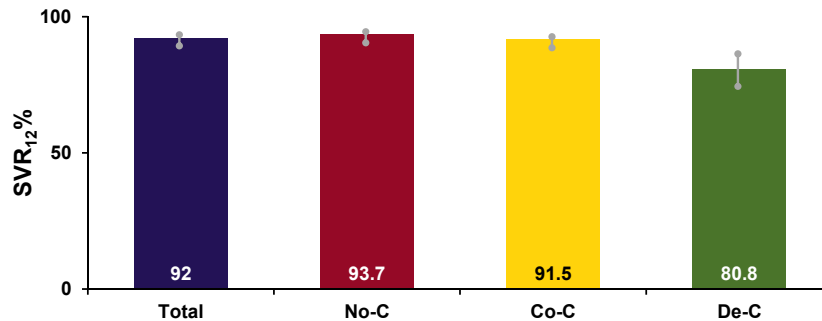
Ribavirin	No. (%)
Yes	627 (30.9)
No	1403 (69.1)

Log₁₀ HCV-RNA
Median = 6.3
IQR = 5.8 – 6.7



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Treatment Outcomes by Severity of Liver-Disease



No-C = no cirrhosis
Co-C = compensated cirrhosis
De-C = decompensated cirrhosis

Decompensated cirrhosis, and therapy with SOF+SMV, SOF+RBV, and SMV+DCV were independently associated with treatment failure

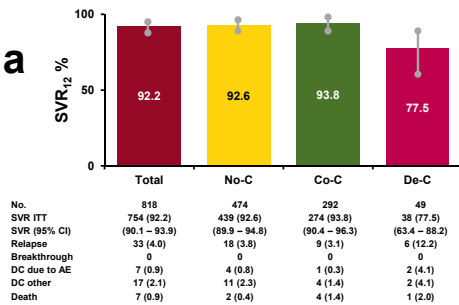
No.	2030	1125	754	146
SVRITT	1867 (92.0)	1054 (93.7)	690 (91.5)	118 (80.8)
SVR (95% CI)	(90.7 – 93.1)	(92.1 – 95.0)	(89.3 – 93.4)	(73.5 – 86.9)
Relapse	89 (4.4)	36 (3.2)	36 (4.8)	17 (11.6)
Breakthrough	5 (0.2)	3 (0.3)	1 (0.1)	1 (0.7)
DC Due to AE	14 (0.7)	7 (0.6)	5 (0.7)	2 (1.4)
DC Other	36 (1.8)	23 (2.0)	10 (1.3)	3 (2.0)
Death	19 (0.9)	2 (0.2)	12 (1.6)	5 (3.4)

* Severity of liver disease was not evaluated in 5 patients

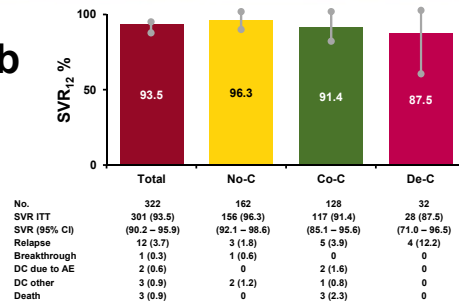
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Treatment Outcomes by HCV Genotype

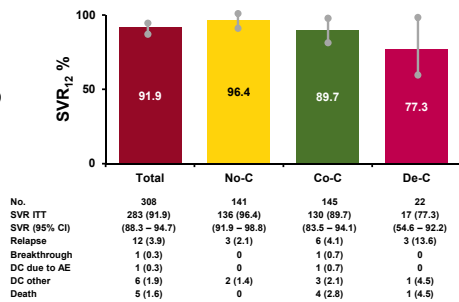
G1a



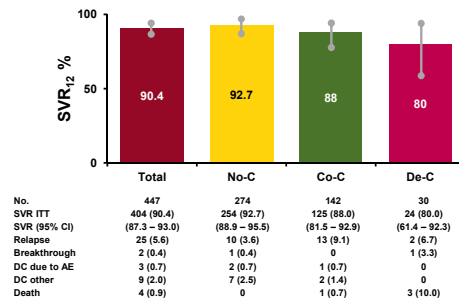
G1b



G3



G4



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Factors Associated with Treatment Failure by Logistic Regression Analysis

Variable	Univariate analysis			Multivariate analysis		
	OR	95% CI	P	OR	95% CI	P
Female sex	0.66	0.43 – 1.03	0.068	0.67	0.43 – 1.04	0.079
No cirrhosis	Ref.			Ref.		
Comp. cirrhosis	1.37	0.96 – 1.95	0.074	1.26	0.88 – 1.82	0.198
Dec. cirrhosis	3.52	2.18 – 5.67	<0.001	2.29	1.30 – 4.05	0.004
Hep. carcinoma	5.87	1.98 – 17.40	0.001	2.81	0.84 – 9.36	0.091
DSV+OBV/PTV/r	Ref.			Ref.		
SOF/LDV	1.23	0.70 – 2.16	0.469	1.14	0.65 – 2.02	0.634
SOF+DCV	1.54	0.79 – 2.98	0.196	1.31	0.67 – 2.56	0.429
OBV/PTV/r	1.38	0.54 – 3.52	0.490	1.49	0.58 – 3.82	0.396
SOF+SMV	5.21	2.45 – 11.10	<0.001	3.69	1.66 – 8.23	0.001
SOF+RBV	4.64	1.63 – 13.23	0.004	3.54	1.20 – 10.41	0.021
SMV+DCV	16.26	2.14 – 123.62	<0.001	12.06	1.54 – 9.40	0.018

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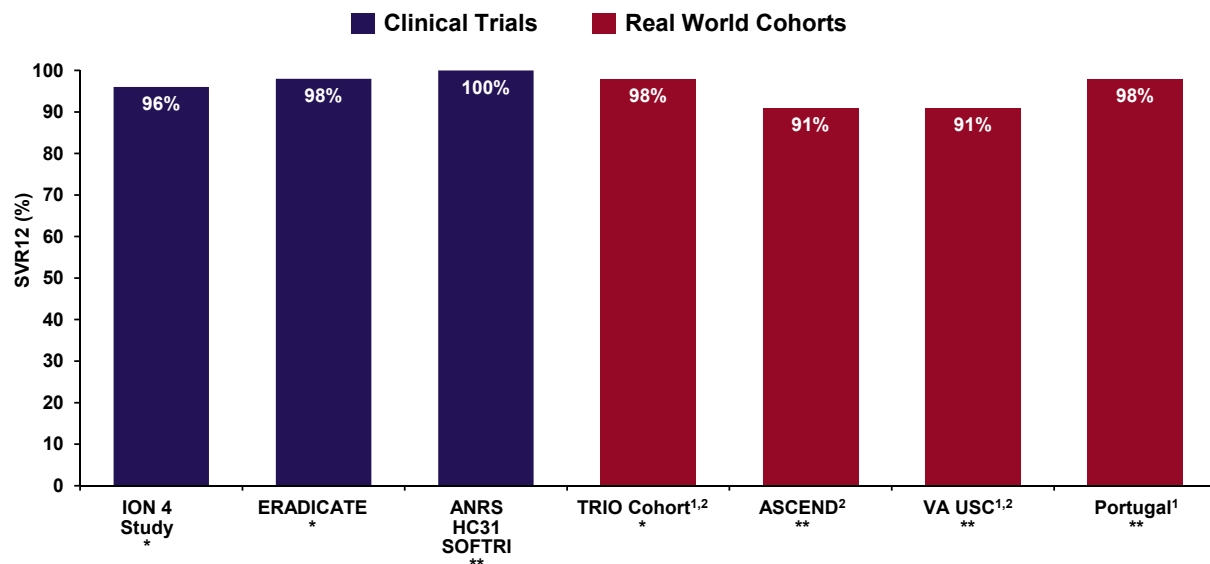
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Real World Effectiveness of Ledipasvir/Sofosbuvir (LDV/SOF) in Patients Coinfected With HCV and HIV-1: A Comparative Analysis of Clinical Trials with Four Real World Cohorts

S. Naggie, E. Rosenthal, S. Kattakuzhy, J. McGinnis, S. Naik, M. Natha, J. Llewellyn,
R. Haubrich, A.O. Osinusi, L.M. Stamm, C. Cooper, D.T. Dieterich, M.S. Sulkowski

Abstract 892

SVR12 in GT 1 HIV/HCV Coinfected Patients Treated with LDV/SOF for 12-24 Weeks: Clinical Trials Compared to Real-World Cohorts



¹ITT analysis in GT1 patients; ²ITT analysis; ** Per Protocol; ¹±RBV; ² small number of patients may have received 8 weeks of LDV/SOF
Naggie S, et al. 67th AASLD; Boston, MA; November 11-15, 2016; Abst. 892.

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SVR12 Rates under DAA-based HCV Therapy from the National German Cohort Study: Does HIV Co-Infection Impair the Response to DAA Combination Therapy?

J.K. Rockstroh, T. Lutz, S. Mauss, C. Cordes, H. Hillenbrand, A. Moll, H. Pfeiffer-Vornkahl,
H. Butzbach, M. Cornberg, M.P. Manns, A. Baumgarte

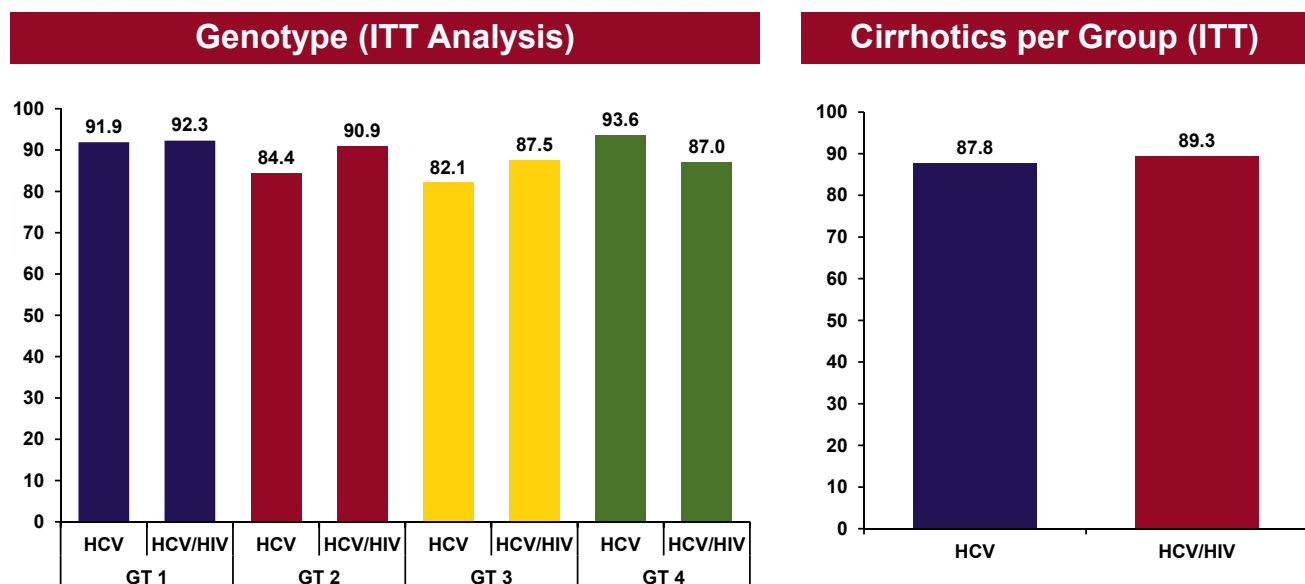
Abstract 907

Does HIV Co-infection Impair the Response to DAA Combination Therapy?

- Overall, 488 HIV/HCV coinfectd and 5,657 HCV mono infected subjects were included into this analysis
- HIV coinfectd patients had good CD4-counts at baseline (63% >350 CD4-cells/ μ l; only 2.6% had a CD4-count below 200/ μ l)

Baseline Characteristics: ITT Population	HCV Mono Infection (n=5657)	HIV/HCV Coinfection (n=488)
Male (%)	57.2	84.7
Age (mean +/- SD)	53.8 +/- 12.5	46.5 +/- 9.0
Cirrhosis (%)	29.4	17.2
Genotype (GT) 1 (%) / GT 2 (%) / GT 3 (%) / GT 4 (%)	78.6 3.9 13 3.8	76.8 2.2 4.9 15.7
HCV Treatment-naïve	51.4	53.5
LDV/SOF +/- RBV // or DAC + SOF +/- RBV // or OBV/PTV/r+DSV ± RBV for GT1 treatment (%)	58.4 11.9 15.1	67.7 8.8 9.4
SOF + RBV // SOF + PegIFN + RBV // SOF + DAC // SOF/LDV + RBV for GT3 (%)	29.2 25.7 22 8.5	45.8 12.5 16.7 12.5
SOF + PegIFN + RBV // or LDV/SOF +/- RBV // or OBV/PTV/r + RBV for GT4 treatment (%)	13.2 42.1 27.3	15.6 44.2 28.6

SVR12 Results by Genotype (ITT Analysis) and SVR12 Response in Cirrhotics per Group (ITT)



Rockstroh J, et al. 67th AASLD; Boston, MA; November 11-15, 2016; Abst. 907.

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