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Abstract # 0571

Real-world effectiveness of Glecaprevir/Pibrentasvir for Hepatitis C Virus Infection

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Background and Aim

- Glecaprevir and pibrentasvir (GLE/PIB) are direct-acting antiviral agents (DAAs) against hepatitis C virus (HCV) with pan-genotypic activity and a high barrier to resistance.
- There are few real-world data on the effectiveness GLE/PIB for treatment of chronic hepatitis C.
- We evaluated the effectiveness and safety of GLE/PIB in a large prospective registry HCV-infected individuals with/without coinfection by HIV and receiving DAAs for HCV infection.

Methods

RUA-VHC (Madrid Registry of Use of DAA for HCV)

- Prospective registry of adults (≥18 years) undergoing therapy with DAAs for HCV infection in the region of Madrid (*Hepatology 2018; 68: 32; Open Forum Infect Dis 2019; 6: ofz214.)*
  - Madrid-CoRe (Madrid Coinfection Registry)
  - Madrid-MoRe (Madrid Monoinfection Registry)
- Compulsory for all hospitals from the Madrid Regional Health Service (SERMAS)

Key inclusion and exclusion criteria

- Once-daily treatment with 3 tablets of the combination of GLE/PIB (total dose: 300 mg/120 mg) for HCV
- Scheduled to finish Rx on or before February 1, 2019
- Retreatment after all-oral DAAs were excluded

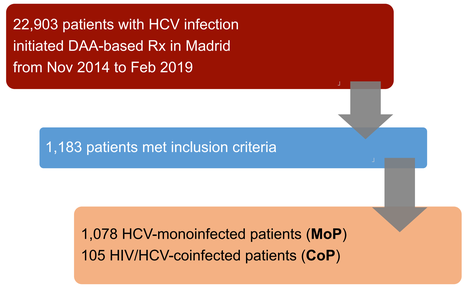
Primary endpoint

- Week 12 sustained viral response (SVR_{12}) by intention-to-treat analysis (ITT) and by modified ITT (m-ITT), excluding patients who discontinued therapy for reasons other than adverse events (AEs)

Secondary endpoints

- Viral relapse
- Viral breakthrough
- Discontinuation of treatment due to AEs
- Discontinuation of treatment for reasons other than AEs

Flow chart

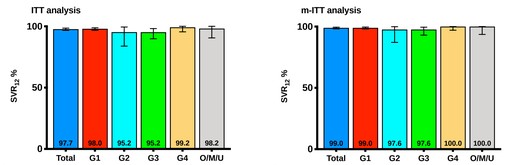


HIV-related variables in HIV/HCV coinfected patients

Variables	Total N=105
HIV risk factor – n (%)	
Injection drug use	53 (50.5)
Men who have sex with men	34 (32.4)
Heterosexual relations	5 (4.8)
Other/unknown	13 (12.4)
CDC clinical category – n (%)	
A	46 (43.8)
B	15 (14.3)
C	22 (20.9)
Unknown	22 (20.9)
Baseline CD4+/mm^3 – n (%)	
Unknown	13 (12.4)
Known	92 (87.6)
Median (IQR)	687 (504-973)
HIV-RNA – n (%)	
Unknown	11 (10.5)
Known	94 (89.5)
Detectable	6 (6.4)
Undetectable	88 (93.6)

Variables	Total N=105
ART – n (%)	
No	14 (13.3)
Yes	91 (86.7)
ART regimen before DAA – n (%)	
2nRTI+1 INSTI	72 (79.1)
2nRTI+1nnRTI	17 (18.7)
Other	2 (2.2)
ART change prior to DAA Rx – n (%)	
No	61 (67.0)
Yes	26 (28.6)
Unknown	4 (4.4)

Treatment outcomes of GLE/PIB (300 mg/120 mg) for 12 weeks by HCV Genotype



O/M/U = Other/mixed/unknown

m-ITT analysis = exclusion of patients with DC for reasons other than AE

Conclusions

1) In this large prospective real-life cohort of patients with hepatitis C, treatment with GLE/PIB led to SVR rates of almost 98% by ITT analysis and 99% by m-ITT analysis.

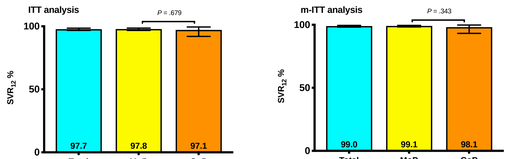
2) Treatment with GLE/PIB was highly efficacious across all genotypes and in the presence of HIV infection or liver cirrhosis.

Characteristics of the study population

Variables	MoP N = 1078	CoP N =105	*P*	Total N= 1183
Age – median (IQR)	55 (49-62)	49 (44-53)	<.001	54 (48-61)
Male sex – n (%)	535 (49.6)	77 (73.3)	<.001	612 (51.7)
Prior anti-HCV therapy – n (%)	99 (9.2)	12 (11.4)	.451	111 (9.4)
Genotype – n (%)			<.001	
1	771 (71.5)	66 (62.9)		837 (70.7)
2	40 (3.7)	2 (1.9)		42 (3.5)
3	117 (10.8)	9 (8.6)		126 (10.6)
4	95 (8.8)	26 (24.8)		121 (10.2)
Other/mixed/unknown	55 (5.1)	2 (1.9)		57 (4.8)
HCV RNA Log IU/mL – Median (IQR)	6.2 (5.7-6.7)	6.2 (5.5-6.6)	.112	6.2 (5.7-6.7)
Cirrhosis – n (%)	80 (7.4)	3 (2.9)	.106	83 (7.0)
Transient elastography – n (%)				
Performed	1029 (95.5)	100 (95.2)		1129 (95.4)
Stiffness kPa – Median (IQR)	6.0 (4.8-7.7)	5.6 (4.4-7.2)	.126	6.0 (4.8-7.7)
Duration of therapy				
8 wk	964 (89.4)	99 (94.3)	.128	1063 (89.9)
12 wk	109 (10.1)	6 (5.7)		115 (9.7)
16 wk	5 (0.5)	0		5 (0.4)

MoP = HCV monoinfected patients. **CoP** = HIV/HCV coinfected patients

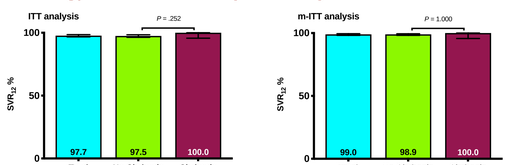
Treatment outcomes of GLE/PIB (300 mg/120 mg) for 12 weeks by HIV status



MoP = HCV monoinfected patients
CoP = HIV/HCV coinfected patients

m-ITT analysis = exclusion of patients with DC for reasons other than AE

Treatment outcomes of GLE/PIB (300 mg/120 mg) for 12 weeks by severity of liver disease



Cirrhosis = liver biopsy, transient elastography stiffness >12.5 kPa), or diagnosis based on clinical/biological findings

m-ITT analysis = exclusion of patients with DC for reasons other than AE

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