The SVR10K Hepatitis C study: Final results show 98.9% SVR in 7,000 patients treated with SOF/VEL in Asia, Latin America, Middle East, Nordic and Southern Europe

Poster WED-276

SVR10K Study

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Conclusions

- SVR10K study have included more than 7,000 patients from Asia, Middle Eastern and Latin-American regions, as well as Nordic/South Europe regions.
- SVR was achieved in 99% of the treated population, with SVR rates ranging from 97% to 100% in all sites.
- SVR kept high (98%) in the concomitant presence of GT3 and a cirrhotic status for the overall population.
- In 24% of the patients with available Time to Treatment (TT) initiation (n=4,744; 68%), the DAA was initiated in ≤30 days.

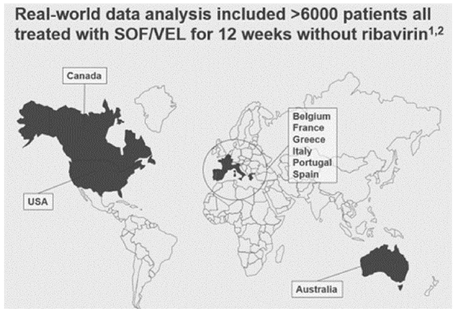
Plain Language Summary

- Results on treatment effectiveness in these new geographies did not differ from real world studies of patients in Western countries, reinforcing the efficacy of pangenotypic/panfibrotic/ pangeographic DAA therapy such as SOF/VEL and supporting the global applicability of HCV treatment guidelines.
- There is a room for improvements in the time to treatment initiation.

Introduction

- A previous real-world data (RWD) analysis demonstrated high effectiveness of sofosbuvir/velpatasvir (SOF/VEL) without ribavirin (RBV) in more than 6,000 HCV patients from different clinical cohorts across Australia, Canada, Europe & USA[1,2] (**Figure 1**).

Figure 1. Previously published RWD analysis in Western countries and Australia



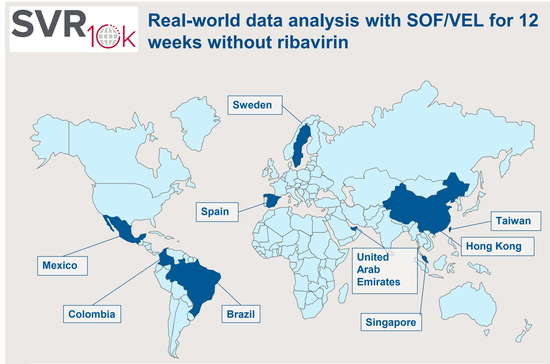
- In that former analysis, irrespective of age, male patients were more likely to have advanced fibrosis and infection with HCV GT 3, and median time to treatment initiation was numerically shorter in male patients across the age spectrum[2].
- The aim of this large real-world analysis was to evaluate both patient and treatment characteristics in a large global cohort of HCV patients treated with SOF/VEL across five diverse global regions in Asia, Middle Eastern, Europe and Latin-American regions (the SVR10K study).

Methods

- This analysis included patients ≥ 18 years treated with SOF/VEL without ribavirin (RBV) for 12 weeks from 13 sites across Brazil, Colombia, Hong Kong, Mexico, Singapore, Sweden, Spain, Taiwan, and the United Arab Emirates (**Figure 2**).
- Baseline characteristics included age (in categories </≥50 yo), sex, being treatment experienced (TE), presence of cirrhosis (F4, not decompensated), genotype, coinfections (HBV, HDV, HIV), time to treatment initiation (TTI) from HCV diagnosis were described, along with sustained virologic response rates (SVR) (**Figure 2**).

Methods (cont.)

Figure 2. SVR10K Study: Sites participating, inclusion criteria, assessments and analysis populations



Individuals with HCV (N=7,027)

- ≥18 years
- Treated with SOF/VEL for 12 weeks, without ribavirin
- General and vulnerable populations (people who inject drugs, homeless people, people in prison, people with mental disorders)
- No history of cirrhotic decompensation
- No prior NS5A inhibitor exposure

Assessments

- Patient characteristics (demographics including </≥50 yo, HCV genotype, liver status, mental health, drug use)
- Presence of other viral coinfections (HIV, HBV, HDV)
- Time to treatment, defined as the time from HCV RNA diagnosis to DAA initiation
- SVR after end of treatment

Analysis Populations

- **Overall:** all patients including those with virological failure, non-virological and unknown reasons for not achieving SVR
- **Effectiveness:** excluded patients who did not have valid SVR status because of non-virological or unknown reasons

Results

- Overall, 7,027 patients were included from the 5 regions. Median age in the overall population was 55 years [IQR 46-64]; highest in Asian sites with 57 years [IQR 48-66]; lowest in Middle Eastern (ME) site with 31 years [IQR 27-52]. Patients over 50 y.o. represented two thirds (66%) of the overall population, with the highest percentage in Asian and Southern European sites (71%) and lowest in the ME site (28%). Patients were mainly male (65%), with the highest % of female in LATAM (49%) (**Table 1**).
- Overall, HIV, HBV and HDV coinfection was reported, respectively, in 4.5%, 3.3%, and 0.1%. In South Europe, HIV co-infection reached 15%. Cirrhosis was reported in 21.5% of the overall population, with the highest rate in Latin American region (34%). Regarding HCV genotypes, overall GT 1 was the most prevalent; except for the Nordics where GT 3 was the most prevalent genotype (57%). Overall, 5% of the population reported being treatment experienced, with the highest rate in Nordics (11%) and lowest rate in Middle East (0%) (**Table 1**).
- The Time to Treatment initiation (TTI) was available in 68% (n=4,744) of the sample, with 24% treated in ≤30 days. Asian, Latin America and South European regions had the highest % of patients treated within the first 30 days (**Table 2**).
- In terms of effectiveness, SVR was achieved in 99% of the treated population, with SVR rates ranging from 97.1% to 100% in all sites. This SVR kept high (98%) in the concomitant presence of GT3 and a cirrhotic status for the overall population. Highest SVR (100%) was reported for Middle East and Asian sites (**Table 3**).

Results (Tables)

Table 1. Demographics in the overall population, with minimal and maximum values (and region where those observed)

		Overall n=7,027	Min (Region)	Max (Region)
Age	Mean [SD]	54.8 [13.8]	39.5 [17.3] (ME)	57.0 [12.9] (Asia)
	Median [IQR]	55.1 [46-64]	31.3 [27-52] (ME)	57.0 [48-66] (Asia)
Age group, % (n)	<50 years	34% (2,409)	29% (Asia/South Eu)	72% (ME)
	≥50 years	66% (4,587)	28% (ME)	71% (Asia/South Eu)
Sex, % (n)	Male	65% (4,564)	51% (LATAM)	69% (ME/South Eu)
	Female	35% (2,445)	31% (ME/South Eu)	49% (LATAM)
Coinfections, % (n)	HBV	3.3% (216)	0% (ME)	3.0% (Asia)
	HDV	0.1% (6)	-	0.2% (Asia)
	HIV	4.5% (303)	1.7% (ME)	14.8% (South Eu)
Liver cirrhosis, % (n)	Yes	21.5% (1,341)	18% (Nordics)	33.9% (LATAM)
Genotype, % (n)	GT1	30.2% (2,125)	15.3% (Nordics)	48.7% (ME)
	GT2	16.9% (1,187)	1.7% (ME)	25.8% (Nordics)
	GT3	30.1% (2,117)	14.4% (LATAM)	56.6% (Nordics)
Treatment exp, % (n)	Yes	5% (339)	0% (ME)	11% (Nordics)

n: # of patients; SD: Standard Deviation; IQR: Interquartile Range; TE: Treatment Experienced; HBV: Hepatitis B; HDV: Hepatitis D; HIV: Human Immunodeficiency Virus; South Eu: South Europe; ME: Middle-East; LATAM: Latin American region

Table 2. Time to Treatment Initiation (TT), with minimal and maximum values (and region where those observed)

		Overall n=4,744	Min (Region)	Max (Region)
TT, %	<1 day	10.4%	5.1% (LATAM)	17.8% (Asia)
	1-7 days	4.6%	0% (ME)	11.8% (LATAM)
	8-30 days	8.9%	1.5% (Nordics)	14.4% (South Eu)
	31-90 days	9.7%	6% (Asia)	40.3% (ME)
	91-180 days	9.9%	4.5% (Asia)	24.4% (ME)
	> 180 days	56.7%	13.4% (ME)	77% (Nordics)

TT: Time to Treatment DAA initiation; n: # of patients

Table 3. SVR in the effectiveness population, with minimal and maximum values (and region where those observed)

		Overall n=6,461	Min (Region)	Max (Region)
SVR (mITT)*, % (n)**	SVR overall	99% (6,387)	97% (Nordics)	100% (ME)
	SVR in GT3	98% (1,989)	96% (Nordics)	100% (ME/Asia)
	SVR in CC	99% (1,246)	96% (Nordics)	100% (ME/Asia)
	SVR in GT3 & CC	98% (406)	93% (Nordics)	100% (ME/Asia)

n: # of patients; SVR: Sustained Virological response (rounded); GT3: Genotype 3 HCV infection; CC: Cirrhotic patients; ***Within effectiveness population only

EASL Session: Poster - Viral hepatitis C: Therapy and resistance

References: **1.** Mangia A et al. *Liver Int* 2020;40:1841-52; **2.** Mangia A et al. *EASL 2022*; Poster FRI384

Acknowledgments: We extend our thanks to the patients, their families, and all participating investigators. This study was funded by Gilead Sciences, Inc. Study implementation, data analysis, editing and production assistance were provided by CERTARA, and funded by Gilead Sciences, Inc.

Disclosures: LC, CH are employees and shareholders of Gilead Sciences, Inc. AC, MM, AK are employees of Certara and Certara is a paid consultant to Gilead Sciences, Inc . MLY, reports grants from: AbbVie, Gilead, Merck and Roche diagnostics; consulting fee from: AbbVie, BMS, Gilead, Roche and Roche diagnostics; speaking and support fees from: AbbVie, BMS, Eisai, Gilead, Roche and Roche diagnostics. GW, reports grants and support fee from: Gilead Science; consulting fee from: AZ, Gilead Sciences, Janssen and GSK; speaking fee from: Abbott, AbbVie, Ascletis, BMS, Echosens, Gilead Science, Janssen, Roche. MFH, reports speaking fee from: Grünenthal Mexico, Schwabe Pharma México; support fee from: Grupo MedifarmaS.A. de C.V. MA, reports speaking and support fees from: Gilead Sciences. JGS, reports grants fee from: Gilead Science; consultant and speaker fees from: AbbVie and Gilead Sciences. MC, reports consultant and speaker fees from: Gilead, Advanz Pharma, Roche; Grants from: Gilead Sciences. SA, reports participation in Gilead Science advisory board HDV, no fee reported. HKK, reports grants from: Gilead Science (Nordic). KL, reports no conflicts.

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