Description of age, sex, and characteristics of Hepatitis C patients in the SVR10K study: A real-world SOF/VEL analysis performed across five global regions

Poster THU-374

SVR10K Study

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Conclusions

- In 6,095 patients with SVR outcomes (effectiveness population), SVR was greater than 98%, without differences for sex or age groups over and under 50 years.
- Although in the overall cohort (6,633 patients) there were more male than females (66% vs 34%), in patients over 50 years the difference tended to be diluted (63% vs 37%).
- In both sexes, GT3 was more prevalent in patients over 50 years. Males more often had GT3 than females (77% vs 23%).
- No difference by sex was observed for patients with compensated cirrhosis (male 20% vs female 22%).
- Time to treatment initiation ≤ 30 days with the HCV therapy was more likely in females compared to males; for both aged over 50 years (25% vs 15%) and under 50 years (17% vs 11%) .

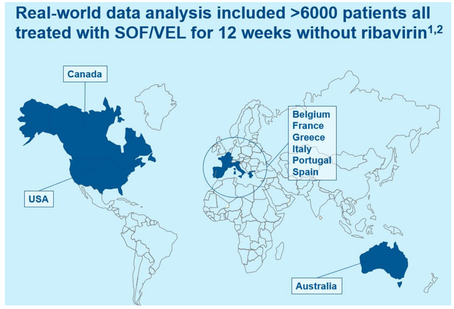
Plain Language Summary

- The SVR10K study confirms the high effectiveness of using SOF/VEL without RBV in diverse populations globally, with real-world SVR higher than 98% across diverse age, sex and geographic groups. Results in these new geographies did not differ from previous 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.

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



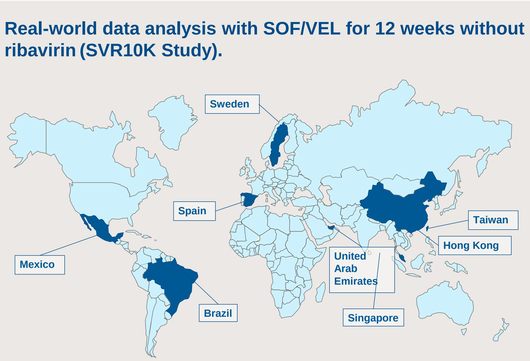
- In that former analysis, irrespective of age, male patients were more likely to have advanced fibrosis and infection with HCV GT 3, and median time to treatment initiation was numerically shorter in male patients across the age spectrum[2].
- The aim of this large real-world analysis was to evaluate differences in outcomes by sex and age characteristics among a pool of of HCV patients treated with SOF/VEL without RBV in an extended geographical initiative across multiple diverse populations in Western countries, Asia, Middle Eastern and Latin-American regions (the ongoing SVR10K study).

Methods

- This (ongoing) analysis included patients ≥ 18 years treated with SOF/VEL without ribavirin (RBV) for 12 weeks from 10 sites across Brazil, 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) at 4, 12, and 24 weeks).

Methods (cont.)

Figure 2. SVR10K Study (On-going Study): Sites participating, inclusion criteria, assessments and analysis populations



Individuals with HCV (N=6,633 in April 2024)

- ≥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

- Among 6,633 patients, 66% (4,348) were males and 34% (2,267) were females, with 71% females vs 62% males being ≥50 yo (p<0.001) (**Table 1**).
- Coinfections were numerically more prevalent in males (HIV 5.3% vs 2.3%, NS; HBV 3.6% vs 3.0%, NS), with statistically significant difference for HDV (0.2% vs 0.1%, p<0.001). No differences were observed in terms of Treatment Experienced (4.7% male vs 3.7% in female, NS), irrespective of being over or under 50 yo (**Table 1**).
- In both sexes, GT3 was more prevalent in over 50 yo. Male patients more often had GT3 vs females (36.4% vs 20.9%, p<0.001); these differences were seen in both age groups, over and under ≥50 yo. No differences by sex was observed for patients with compensated cirrhosis (22.0% male vs 20.0% female, NS) (**Table 1**).
- Time to treatment initiation with the HCV therapy was shorter in females; for aged over 50 yo (25.3% in females vs 14.6% in males, p<0.001) as well as for aged under 50 yo (17.0% in females vs 10.9% in males, p<0.001) (**Table 2**).
- In 6,095 patients with SVR outcomes (effectiveness population), both sex and age groups had SVR greater than 98% (99.0% in females vs 98.7% in males), without statistically significant differences for aged over or under 50 yo (**Table 3**).

Results (Tables)

Table 1. Demographics for female and male patients in the overall population

		Female n=2,267	Male n=4,348	p value
Age	Mean [SD]	58.0 [14.8]	53.0 [12.8]	**<.0001**
	Median [IQR]	59.3 [47.7; 68.5]	53.7 [44.8; 61.3]	**<.0001**
Age group, n (%)	<50 years	659 (29.1%)	1,648 (37.9%)	**<.0001**
	≥50 years	1,608 (70.9%)	2,699 (62.1%)	
Coinfections, n (%)	HBV	65 (3.0%)	150 (3.6%)	0.1869
	HDV	1 (0.1%)	5 (0.2%)	**<.0001**
	HIV	50 (2.3%)	218 (5.3%)	0.2468
TE, n (%)	Overall	82 (3.7%)	196 (4.7%)	0.0724
	TE in age <50 y	21 (3.3%)	60 (3.8%)	0.5473
	TE in age ≥50 y	61 (3.9%)	136 (5.3%)	0.0521
Genotype 3*, n (%)	Overall	473 (20.9%)	1,584 (36.4%)	**<.0001**
	GT3 in age <50 y	272 (41.3%)	787 (47.8%)	**0.0048**
	GT3 in age ≥50 y	201 (12.5%)	796 (29.5%)	**<.0001**
Fibrosis stage F4, n (%)	Overall	206 (20.0%)	620 (22.0%)	0.1851
	F4 in age <50 y	69 (14.2%)	205 (16.3%)	0.276
	F4 in age ≥50 y	137 (25.3%)	415 (26.6%)	0.5356

n: # of patients; SD: Standard Deviation; IQR: Interquartile Range; TE: Treatment Experienced; HBV: Hepatitis B; HDV: Hepatitis D; HIV: Human Immunodeficiency Virus; * All genotype 3 subtypes are included; F4: Fibrosis stage 4; y: years

Table 2. Time to Treatment Initiation (TT)

		Female n=2,658	Male n=4,107	p value
Time to Treatment (TT), n (%)**	<1 day	230 (10.8%)	257 (6.3%)	**<.0001**
	1-7 days	104 (4.9%)	101 (2.5%)	
	8-30 days	185 (8.6%)	215 (5.2%)	
	31-90 days	159 (7.4%)	258 (6.3%)	
	91-180 days	136 (6.4%)	238 (5.8%)	
	>180 days	750 (35.1%)	1,767 (43.0%)	
	Missing	575 (26.9%)	1,271 (30.9%)	
TT ≤ 30 days, n (%)**	In age <50 y	112 (17.0%)	179 (10.9%)	**<.0001**
	In age ≥50 y	407 (25.3%)	394 (14.6%)	**<.0001**

n: # of patients; y: years; **Missing values used for percentage calculation

Table 3. SVR in the effectiveness population

		Female n=2,066	Male n=4,029	p value
SVR (mITT)*, n (%)**	SVR overall	2,045 (99.0%)	3,978 (98.7%)	0.3937
	SVR in <50 y	594 (98.0%)	1,496 (98.2%)	0.7475
	SVR in ≥50 y	1,451 (99.4%)	2,481 (99.0%)	0.2534

n: # of patients; SVR: Sustained Virological response; y: years; ***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

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