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 (Figure 1).

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

Real-world data analysis included >6000 patients all treated with SOF/VEL for 12 weeks without ribavirin (SOF/VEL study).

In that former analysis, irrespective of age, male patients were more likely to have advanced fibrosis and infection with HCV GT 3, and mean time to treatment initiation was numerically shorter in male patients across the age spectrum. The aim of this large real-world analysis was to evaluate differences in outcomes by sex and age characteristics among a pool of 6,633 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).

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 pan-genotypic/pan-fibrotic agents such as SOF/VEL and supporting global applicability of HCV treatment guidelines.

Methods

This (ongoing) analysis included patients ≥18 years treated with SOF/VEL without RBV for 12 weeks from 10 sites across Brazil, Hong Kong, Mexico, Singapore, Sweden, Spain, Taiwan, and the United Arab Emirates (Figure 2).

The baseline characteristics included age (in categories <≥50yo), sex, being treatment-naive, cirrhosis (F4), genotype, presence of other viral coinfections (HIV, HBV, HDV), time to treatment initiation (TTI) from HCV diagnosis, treatment-experienced (TE), past episodes of decompensated cirrhosis (≥180 days), prior NS5A inhibitor (F4 in age ≥50 yo), fibrosis stage in patients ≥50 yo.

Among 6,633 patients, 68% (4,438) were males and 34% (2,267) were females, with 71% females vs 62% males being 50 yo or < (p<0.001) (Table 1).

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

<table>
<thead>
<tr>
<th>Age range</th>
<th>Female</th>
<th>Male</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 yo</td>
<td>2,307</td>
<td>2,151</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥50 yo</td>
<td>2,261</td>
<td>2,322</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

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 yo.
- Although in the overall cohort (6,633 patients) there were more males 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. Male patients more often had GT3 than females (77% vs 23%).
- No difference by sex was observed for patients with compensated cirrhosis (male 29% 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%).

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Table 2. Time to Treatment Initiation (TT)

<table>
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<tr>
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<th>Male</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 yo</td>
<td>230 (10.5%)</td>
<td>257 (12.3%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥50 yo</td>
<td>105 (3.6%)</td>
<td>105 (3.6%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

- No prior NS5A inhibitor exposure
- 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); treatment-experienced (TE) was present in 17.0% in females vs 10.9% in males, p<0.001.
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Table 3. SVR in the effectiveness population

<table>
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<th>Age range</th>
<th>Female</th>
<th>Male</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 yo</td>
<td>2,262 (99.6%)</td>
<td>2,281 (99.6%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥50 yo</td>
<td>2,321 (99.2%)</td>
<td>2,330 (99.2%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

- General and substantial differences (people who inject drugs, homeless people, people in prison, people with mental disorders).
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