Real World Effectiveness of Ledipasvir/Sofosbuvir (LDV/SOF) for 8 Weeks in Patients Coinfected With HCV GT 1 and HIV-1

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Introduction

Ledipasvir/Sofosbuvir (STR)

- Potent antiviral activity against multiple HCV genotypes
- Effective against NS5A/RASs
- High barrier to resistance
- Once-daily, oral fixed-dose (80 mg/400 mg) combination tablet, RBV-free
- Limited DDIs, no food effect

SOF is an NS5B nucleoside polymerase inhibitor

Background

- With the introduction of Direct Acting Antivirals (DAAs), the EASL and AASLD/IDSA/USA Guideline state “HIV/HCV coinfected persons should be treated and retreated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications”.
- LDV/SOF was approved by the FDA and EMA for HIV/HCV coinfection with the same dosage recommendations as in HCV monoinfected patients.
- Real-world cohorts (RWC) have demonstrated excellent efficacy of LDV/SOF for 8 weeks in HCV monoinfected patients.
- The aim of this analysis was to describe the effectiveness of LDV/SOF for 8 weeks in HCV genotype 1 patients with HIV/HCV coinfection in RWC and clinical trials using a pooled analysis.

Objectives

- Describe SVR12 rates in real-world and clinical trial cohorts.
- Describe SVR12 rates in HIV coinfection versus real-world cohorts.

Methods

- Two prospective clinical trials and four real-world cohorts were reviewed and pooled.
- Cohorts with fewer than 15 patients were excluded.

Results

Baseline Demographics

- TDF containing regimen

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cohort</th>
<th>US Discordant</th>
<th>US Concomitant</th>
<th>VA</th>
<th>Prague</th>
<th>Boston</th>
<th>Madrid</th>
<th>Valencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>42 (22.5–58)</td>
<td>42 (22.5–58)</td>
<td>41 (21–71)</td>
<td>41 (21–71)</td>
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<td>41 (21–71)</td>
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<td>41 (21–71)</td>
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<tr>
<td>Sex, n (%)</td>
<td>34 (63)</td>
<td>40 (72.5)</td>
<td>15 (30)</td>
<td>6 (10)</td>
<td>17 (34)</td>
<td>17 (34)</td>
<td>17 (34)</td>
<td>17 (34)</td>
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<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>White</td>
<td>59 (11)</td>
<td>59 (11)</td>
<td>59 (11)</td>
<td>59 (11)</td>
<td>59 (11)</td>
<td>59 (11)</td>
<td>59 (11)</td>
<td>59 (11)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (27)</td>
<td>14 (27)</td>
<td>14 (27)</td>
<td>14 (27)</td>
<td>14 (27)</td>
<td>14 (27)</td>
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Conclusions

- This descriptive analysis demonstrates that SVR rates from RWC are comparable to clinical trials.
- High SVR results in this pooled analysis support the use of LDV/SOF for 8 weeks in HIV/HCV GT 1 coinfected patients.
- In the RWC, SVR rates were high across diverse populations, including Black patients (100%, 35/35) from the EU and US.
- The results support the EASL guidelines which recommends the same treatment regimens for HIV/HCV coinfect and HCV monoinfected persons (A1 GRADE).
- Early LDV/SOF initiation in coinfected patients before the onset of advanced fibrosis leads to high SVR212 and may reduce morbidity & mortality.

References & Disclosures

- P Buggisch, Jasmina Dikic, John J. Kowdley and Gastone Santoro, Research Supported by Gilead, Bristol-Myers Squibb, Merck, Abbvie, and Janssen; No conflict of interest.

* Data available for 19 patients.

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