Real-world effectiveness of ledipasvir/sofosbuvir in hepatitis C virus genotype 1, 2 and 3 infection: single-center experience within Georgian hepatitis C elimination program

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Disclosure

No conflicts of interest to declare
• Effectiveness of ledipasvir/sofosbuvir (LDV/SOF) in HCV genotype 1 infection is well established.

• Few studies assessed LDV/SOF in genotype 2 and 3 infection and data on effectiveness are limited.

• In April 2015, the country of Georgia, with the support of the US CDC and Gilead Sciences, launched a national hepatitis C elimination program.

• Since March 2016, LDV/SOF was recommended for all HCV genotypes within Georgia’s HCV elimination program. We report on real-world effectiveness of LDV/SOF-based regimens for various genotypes in Georgia.
AIM

• The aim of this study was to evaluate the effectiveness of LDV/SOF-based regimens for various genotypes in Georgia.
METHODS

Study population and settings

- Study included 4962 Adult (age ≥18 years) patients receiving HCV care at Infectious Diseases, AIDS and Clinical Immunology Research Center between Mar 2016 – Jun 2017;
- Persons with decompensated cirrhosis were excluded

HCV treatment regimens

- All patients received HCV treatment free of charge within hepatitis C elimination program in accordance with the national treatment protocols.
- Patients received LDV/SOF with or without RBV for either 12 or 24 weeks
- A total of 4962 persons started treatment with LDV/SOF at IDACIRC between March 2016 – June 2017, among them 3908 were assessed for SVR and were included in the analysis.

Statistical analysis

- Sustained virologic response (SVR), defined as undetectable HCV RNA at least 12 weeks after completion of treatment, was the outcome of interest
- Advanced liver fibrosis/cirrhosis was defined as liver stiffness of >9.5 kPa by transient elastography or FIB4 score >3.25.
- Differences in SVR rates were compared using Pearson’s chi-square test
# RESULTS

## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n=3908 TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, median years</strong></td>
<td>43</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>429 (10.9)</td>
</tr>
<tr>
<td>Male</td>
<td>3479 (89.1)</td>
</tr>
<tr>
<td><strong>Mode of HIV transmission, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Injection drug use</td>
<td>2837 (72.6)</td>
</tr>
<tr>
<td>Other</td>
<td>1071 (27.4)</td>
</tr>
<tr>
<td><strong>HCV genotype, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1756 (44.9)</td>
</tr>
<tr>
<td>2</td>
<td>1039 (26.6)</td>
</tr>
<tr>
<td>3</td>
<td>1113 (28.5)</td>
</tr>
<tr>
<td><strong>Treatment regimen, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>LDV/SOF</td>
<td>1698 (43.4)</td>
</tr>
<tr>
<td>LDV/SOF plus RBV (12 wk)</td>
<td>2130 (53.5)</td>
</tr>
<tr>
<td>LDV/SOF plus RBV (24 wk)</td>
<td>80 (2.1)</td>
</tr>
</tbody>
</table>
RESULTS

Treatment Outcomes of LDV/SOF by regimen and cirrhosis status

- **All**: 99.4% (Total), 97.4% (Cirrhosis), 99.7% (No cirrhosis)
- **Genotype 1**: 99.6% (Total), 98.4% (Cirrhosis), 99.8% (No cirrhosis)
- **Genotype 2**: 99.8% (Total), 99.2% (Cirrhosis), 99.9% (No cirrhosis)
- **Genotype 3**: 98.7% (Total), 94.3% (Cirrhosis), 99.5% (No cirrhosis)

Significance:
- **p=0.0001**
- **p=0.0014**
- **p=0.47**
- **p<0.0001**
CONCLUSIONS

• LDV/SOF-based treatment was highly effective in this real-world cohort, including in patients with advanced liver fibrosis/cirrhosis.

• Extremely high cure rates were observed in all genotypes.

• Combination of LDV/SOF/RBV appears to be an effective treatment option not only for genotype 1, but for genotype 2 and 3 infections as well.