Real-world Data on HIV-Positive Patients with HCV Treated with Sofosbuvir and/or Simeprevir

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Background

naïve

FIB-4 score, Treatment Experience, and SVR12 Rate by Genotype and Regimen

<table>
<thead>
<tr>
<th>Genotype</th>
<th>N (%)</th>
<th>FIB-4 23.25, n (%)</th>
<th>Naïve, n (%)</th>
<th>SVR12 Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>65/78 (83%)</td>
<td>36/65 (55%)</td>
<td>27/65 (42%)</td>
<td>39/54 (72%)</td>
</tr>
<tr>
<td>SMV/SOF ± RBV</td>
<td>34/78 (44%)</td>
<td>19/34 (56%)</td>
<td>16/34 (47%)</td>
<td>26/29 (89%)</td>
</tr>
<tr>
<td>SOF/RBV</td>
<td>31/78 (40%)</td>
<td>17/31 (55%)</td>
<td>11/31 (35%)</td>
<td>13/25 (52%)</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>7/80 (9%)</td>
<td>2/7 (29%)</td>
<td>2/7 (29%)</td>
<td>3/6 (50%)</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>6/80 (8%)</td>
<td>3/6 (50%)</td>
<td>4/6 (66%)</td>
<td>2/4 (50%)</td>
</tr>
</tbody>
</table>

Methods

- Since December, 2013, data have been collected on patients at Mount Sinai Hospital with chronic HCV prescribed SMV and/or SOF.
- Records of 594 HCV-positive patients have been reviewed.
- Data have been collected on 78 HIV-positive patients with chronic genotype 1, 2, or 3 HCV infection who initiated: SMV/SOF with or without RBV
- In this study, advanced fibrosis/cirrhosis was defined by biopsy and/or a FibroScan score ≥ 13.5 kPa and/or a FIB-4 score ≥ 3.25.
- Week 2 on-treatment responses were analyzed.
- Week 4 and week 12 post-end-of-treatment (EOT) responses were analyzed to determine the SVR4 and SVR12 on a per-protocol basis.
- Week 2, SVR4 and SVR12 rates among the co-infected patients were compared to those HCV mono-infected patients placed on SMV- and/or SOF-containing regimens during the same period.

Regimens by Genotype

<table>
<thead>
<tr>
<th>Genotype</th>
<th>SMV/SOF +/- RBV for 12 weeks for 34 patients (44%)</th>
<th>SOF/RBV for 24 weeks for 31 patients (40%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>- 65 SMV/SOF patients had data on baseline CD4 counts</td>
<td>- Median CD4 count: 490; IQR: 326-629</td>
</tr>
</tbody>
</table>

Baseline HIV Characteristics

- 5 patients had CD4 count < 200; only 3 were on HAART

HIV Viral Load

- Median CD4 count: 490; IQR: 326-629
- 5 patients had CD4 count < 200; only 3 were on HAART
- 60-year-old known Child-Pugh Class C cirrhotic who, at baseline, had platelets of 55, a total bilirubin of 3.9, an INR of 2 and an albumin of 1.6
- He was initially prescribed SMV/SOF
- He further decompensated 4 weeks into therapy with development of ascites, spontaneous bacterial peritonitis (SBP) and an elevated total bilirubin to 13.2 mg/dL.
- He was subsequently changed to SOF/RBV 12 weeks after his DAA regimen was changed, he was admitted with fatigue and electrolyte disturbances.
- Five days after admission, he died of sepsis secondary to an ESBL E. coli. Source was presumptively SBP.

Serious Adverse Events

- SMV/SOF patients
- One patient died
- There were 4 early treatment discontinuations due to expected side effects from RBV such as declining hemoglobin values and worsening depression

SMV/SOF Treatment Failures

- 45 y.o. male, on HAART, with liver transplant in 2010, on long-standing mycophenolate mofetil and tacrolimus. F3, per liver biopsy, HCV treatment experienced.
- 52 y.o. male, on HAART, suspected cirrhosis, HCV previously treated naive.
- 49 y.o. female, not on HAART, CD4 count 193, 29%, HCV viral load < 20, detected, suspected cirrhosis, HCV previously treated experienced.

Conclusions

- Preliminary data indicate that SMV/SOF is a safe and effective option for HIV-positive patients co-infected with genotype 1 HCV who have either 1 fibrosis without cirrhosis or (2) compensated cirrhosis.
- Based on past and current data, SMV should not be used in the setting of decompensated cirrhosis.
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