EFFECTIVENESS AND SAFETY OF NEW DIRECT ACTING ANTIVIRALS FOR THE TREATMENT OF HEPATITIS C INFECTION: PRELIMINARY DATA IN A COINFECTED HIV/HCV POPULATION


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OBJECTIVES

To provide preliminary data on effectiveness and safety of DAAs for the treatment of Hepatitis C infection in the HIV/HCV coinfected population, under routine clinical practice.

METHODS

Design: Observational, descriptive, prospective study.
Inclusion criteria: coinfected patients who have finished their treatment with DAAs before 09/10/2015.

Variables:
- Demographic and baseline clinical data: HCV genotype, sex, prior response to HCV treatment, grade of fibrosis, presence or absence of decompensated cirrhosis, blood count, ALT, AST.
- Effectiveness analysis: Viral Load (VL) at the end of the treatment or Sustained Virologic Response at week 12 if available.
- Safety analysis: adverse drug events (ADEs), including laboratory abnormalities.

RESULTS

• 95 patients were included, of whom 67 (70.5%) were men with an average (SD) age of 51 (5.4) years old. HIV viral load was < 37 copies/mL in 96.7% of patients. The median CD4 cell count was 492 cells/mL (IQR 266.5-681). Baseline characteristics are shown in the Table.
• The planned duration of AAD treatment was 12 weeks in 56.8% of patients. The selection of treatment (n, %) is shown in Figure 1.

<table>
<thead>
<tr>
<th>Grade of fibrosis</th>
<th>N (%)</th>
<th>Prior Treatment</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>F2</td>
<td>17 (17.9)</td>
<td>Naive</td>
<td>43 (45.3)</td>
</tr>
<tr>
<td>F3</td>
<td>15 (5.8)</td>
<td>PegIFN/RBV</td>
<td>40 (42.1)</td>
</tr>
<tr>
<td>Cirrhotic</td>
<td>62 (65.3)</td>
<td>Triple therapy (protease inhibitor)</td>
<td>12 (12.6)</td>
</tr>
<tr>
<td>Decompensated cirrhosis</td>
<td>15 (15.8)</td>
<td>Genotype, N (%)</td>
<td></td>
</tr>
<tr>
<td>Hepatocellular carcinoma</td>
<td>0 (0)</td>
<td>GT 1a</td>
<td>39 (41.1)</td>
</tr>
<tr>
<td>Liver transplantation</td>
<td>1 (1.1)</td>
<td>GT 3</td>
<td>12 (12.6)</td>
</tr>
</tbody>
</table>

Effectiveness results:
• At the end of treatment, indetectable HCV VL was achieved in 80/83 patients (2 patients died during treatment because of other causes and 1 patient decided to stop treatment). 7/8 patients achieved SVR (no data for SVR still available for the remaining patients).
• Serum transaminases were normalized in 79.6% of patients.

Safety results:
At the end of treatment, no patient had confirmed HIV-1 virologic rebound. No patient discontinued treatment because of ADEs. Only 3 ADEs of grade III were identified (insomnia in 2 patients treated with sofosbuvir and daclatasvir and in 1 patient treated with sofosbuvir/ledipasvir).
Common ADEs of grade I-II identified are shown in Figure 2.

CONCLUSIONS

Preliminary data corroborates high effectiveness and a good safety profile of DAA regimens in HIV/HCV coinfected population.

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