NEW HEPATITIS DRUGS IN A MEDICAID SPECIAL NEEDS POPULATION–A PRELIMINARY REPORT

T Leach, J Moore, S Rambaran, E Leach, J Cohn, N Olivo; JA Ernst

OBJECTIVES

1. To report our initial experiences with direct acting antiviral (DAAs) treatments for Hepatitis C (HCV) in a HIV/HCV co-infected population.
2. To explore how real-world results compare to those reported in clinical trials.

BACKGROUND

Amida Care, a Medicaid Special Needs Plan exclusively designed for people with HIV, has been approving regimens containing DAAs since December 2013. Members in the plan have an average of 7.2 co-morbidities with the top three being: severe mental illness, active drug abuse and Hepatitis C. The Plan’s overall HIV viral suppression rate approaches 70%.

With the advent of DAAs for the treatment of HCV, cure rates reported in clinical trials are well over 95% as measured by sustained virologic response (SVR) at 12 weeks (SVR12). We are reporting here initial results in the first 109 patients treated with DAAs from December 2013 through September 2014.

METHODS

We performed a retrospective record review of HIV/HCV patients receiving DAA treatment for HCV from December 2013 thru September 2014. Only patients who completed treatment and had an end of treatment viral load result or who did not complete treatment are included in this report.

HIV RNA, CD4 Cell counts, HCV RNA, HCV genotypes and fibrosis scores (when available) were collected at baseline as part of the pre-enrollment process in patients who qualified for HCV treatment according to current guidelines (See box to right).

Pharmacy staff monitored baseline characteristics, lab results and adherence from the time HCV treatment was requested through 12 weeks post treatment.

RESULTS

Table 1 - Treatment Status of HIV/HCV Co-infected Health Plan Members treated with DAA's December 2013 through Sept. 2014

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>Number Treated</th>
<th>HCV Treatment Experienced</th>
<th>Treatment naïve</th>
<th>HCV Suppression</th>
<th>SVR at 1 month</th>
<th>End of treatment HCV suppression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sof+Peg+Rib</td>
<td>25</td>
<td>2</td>
<td>22</td>
<td>100%</td>
<td>11</td>
<td>100%</td>
</tr>
<tr>
<td>Sof+Sim+Rib</td>
<td>20</td>
<td>2</td>
<td>18</td>
<td>100%</td>
<td>16</td>
<td>100%</td>
</tr>
<tr>
<td>Sof+Rib</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Sof+Peg+Sim</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Sof+Peg+Rib</td>
<td>15</td>
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<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Sof+Rib</td>
<td>10</td>
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Table 2 - Genotype of DAA Treated Members (n=50)

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Quantity</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a</td>
<td>10</td>
<td>20%</td>
</tr>
<tr>
<td>1b</td>
<td>9</td>
<td>18%</td>
</tr>
<tr>
<td>2a, 2b, 2c</td>
<td>6</td>
<td>12%</td>
</tr>
<tr>
<td>3 and 4</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>

Table 3 - End of Treatment (EOT) Results by Genotype and CD4 Count

<table>
<thead>
<tr>
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<td>11</td>
<td>100%</td>
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<td>20</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Sof+Rib</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Sof+Peg+Sim</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>0%</td>
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CONCLUSION

Preliminary results in a Medicaid HIV/HCV co-infected population show impressive end of treatment HCV suppression rates.

This study is ongoing and final results including SVR12 will be presented at a later time.

RECOMMENDATIONS

Future follow-up evaluations of interest include:

• Assessments of treatment results by treatment regimens including daily oral-only therapies
• Expanding the evaluation to incorporate SVR-12 results
• Investigate the incidence of re-infection
• Identify potential barriers to DAA treatment for those who have not been treated. (Preliminary data is being presented in a poster at this meeting)
• Understand the impact of disease variables (CD4, treatment history and liver fibrosis score) on SVR 12 rates

ACKNOWLEDGEMENTS

The authors wish to thank the entire staff and Board of Directors at Amida Care who made this project possible.

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