Real World Assessment of All-Oral, Sofosbuvir-Based, Hepatitis C Therapy at an Academic Medical Center with Integrated Specialty Pharmacy Services

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BACKGROUND

- The discovery of orally administered, direct acting antiviral (DAA) therapies has revolutionized the treatment of hepatitis C virus (HCV).
- Clinical trials report sustained virologic response (SVR12) rates 12 week post therapy (SVR12) at over 90% with fewer side effects and a shorter treatment duration compared to previous interferon-based standard of care.
- In addition to better efficacy, these new therapies also have limited side effect profiles, which, in turn, improves therapy completion rates.
- However, the strictly controlled environments of these clinical trials brings into question the external validity when considering treatment of the general population.

METHODS

- To evaluate patient outcomes to all-oral, sofosbuvir (SOF)-based, HCV therapies in a real world setting and assess the impact of a clinic-integrated specialty pharmacy on therapy completion.
- IRB-approved, retrospective chart review.

Inclusion Criteria

- ≥18 years of age
- HCV prescription written by Vanderbilt Provider: December 1, 2013 to May 31, 2015
- Receiving HCV regimen consisting of the following:
  - sofosbuvir+ribavirin (S+R)
  - ledipasvir/sofosbuvir (L/S)

RESULTS

<table>
<thead>
<tr>
<th>SVR12 Rates (%)</th>
<th>L/S</th>
<th>L/S+R</th>
<th>S+S</th>
<th>S+R</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/L n=341 (47%)</td>
<td>91</td>
<td>96</td>
<td>100</td>
<td>95</td>
</tr>
<tr>
<td>S/LR n=20 (3%)</td>
<td>86</td>
<td>92</td>
<td>82</td>
<td>76</td>
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<td>S/S n=207 (29%)</td>
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<td>S/R n=149 (21%)</td>
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Adverse Events

Vanderbilt Specialty Pharmacy

- SVR12 Rates
- 97%

Other Specialty Pharmacy

- SVR12 Rates
- 93%

Therapy Discontinuations

Early Discontinuations

- Clinical Trials: 1.4% +0.8% +1.2% +1.2% +1.1%
- Real World: 2% 5% 2% 12% 4%

Real World Reason %

- Side Effects: 63% - 50% 61% 39
- Noncompliance: - - 22% 13
- Poor Response: - - 6 3
- Medication Access: 13 100 50 11 19
- Other: 25 - - - 6

VSP Medication Access

- Patient Access Rate: 100%

VSP Patient Prescription Costs

- Average Out-of-Pocket Cost per Prescription:
  - ledipasvir/sofosbuvir: $52.41
  - simeprevir: $8.13
  - sofosbuvir: $3.30
  - ribavirin: $10.01

CONCLUSIONS

- Despite the medically diverse and largely cirrhotic patient population, the SVR12 rates of all-oral, SOF-based antiviral therapies were comparable to those demonstrated by clinical trials.
- Adverse effects were common but rarely caused early discontinuation.
- Patient utilization of the clinic-integrated Vanderbilt Specialty Pharmacy significantly increased the likelihood of completion of the full course of therapy and also provided patients with 100% access to HCV medications.
- VSP was able to service the majority (67%) of adult Vanderbilt patients treated for HCV while keeping patient pay prescription cost low.