Effectiveness of Ledipasvir/Sofosbuvir and Predictors of Treatment Failure in Members with Hepatitis C Genotype 1: A Retrospective Cohort Study in a Medicaid Population

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Authors

Keywords
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INTRODUCTION

An estimated 2.7 to 3.9 million Americans suffer from chronic HCV infection. The primary goal of therapy in chronic HCV infection is eradication of HCV RNA, which is predicted by achievement of SVR12. Current treatment guidelines recommend treatment with antiviral medications for all patients with chronic HCV infection.1 Hanifa2 (ledipasvir/sofosbuvir) is a combination of DAA agents FDA-approved for the treatment of HCV genotypes 1, 4, 5, and 6 on October 14, 2014.2 Real-world studies of LDV/SOF in the VA system and in academic and community medical centers have shown rates of SVR12 over 90% with 8-week, 12-week, and 24-week courses with and without ribavirin.3 There is an urgent need for real-world effectiveness data in the Medicaid population.

OBJECTIVES

Primary Objective: To evaluate the effectiveness of HCV genotype 1 treatment with LDV/SOF as measured by SVR12 in the Massachusetts FFS and PCC plan population

Secondary Objectives: To evaluate the effectiveness of HCV genotype 1 treatment with LDV/SOF in the subgroups of 12, 24, and 24-week regimens, and to identify predictors of treatment failure

METHODS

This retrospective cohort study utilized clinical and demographic data that is routinely compiled from data submitted by any Massachusetts FFS or PCC plan. The study utilized pharmacy claims data from the MassHealth POPS. Pharmacy claims data was only available for claims billed to a MassHealth FFS or PCC plan. Pharmacy claims data from the MassHealth Pharmacy Online Processing System (POPS) was used to identify members and to extract claims for LDV/SOF during the study period. The inclusion criteria were members over the age of 18 years, diagnosis of HCV genotype 1, completion of at least one treatment course, and treatment for at least 8 weeks. The exclusion criteria included members with a baseline HCV RNA <6 million IU/mL. The study was deemed exempt from institutional review board (IRB) review by the IRB at the University of Massachusetts Medical School.

RESULTS

Table 1. Proportions of Members by Clinical and Demographic Variables, N (%)  

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>LDV/SOF for 8 weeks N=297</th>
<th>LDV/SOF for 12 weeks with ribavirin N=69</th>
<th>LDV/SOF for 12 weeks without ribavirin N=399</th>
<th>LDV/SOF for 24 weeks with or without ribavirin N=31</th>
<th>LDV/SOF total for all members N=796</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male</td>
<td>163 (54.9)†</td>
<td>55 (76.1)†</td>
<td>258 (64.5)†</td>
<td>18 (58.1)†</td>
</tr>
<tr>
<td>Age</td>
<td>141 (47.7)†</td>
<td>14 (10.1)†</td>
<td>141 (35.3)†</td>
<td>13 (41.9)†</td>
<td>302 (38.0)†</td>
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<tr>
<td>&lt;65 years</td>
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<td>≥65 years</td>
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<td>Comorbidities</td>
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<td>HIV</td>
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<td>SUD</td>
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<td>Mean age, in years (SD)</td>
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<td>Age</td>
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DISCUSSION

The proportion of members who achieved SVR12 was similar to the proportion of members who achieved SVR12 in other real-world studies of LDV/SOF Table 2.1,2 LDV/SOF is FDA-approved as an 8-week regimen in treatment-naive, non-cirrhotic members with a baseline HCV RNA <6 million IU/mL. Current treatment guidelines note that preliminary real-world data for the comparative effectiveness of 8-week, 12-week, and 12-week regimens in this population is inconclusive, and leave the selection of treatment duration to the discretion of the prescriber.2,3 A high proportion of treatment-naive, non-cirrhotic, HCV-naive-infected members with a baseline HCV RNA <6 million IU/mL who received 8 weeks of LDV/SOF achieved SVR12. These results are comparable to those seen with 8-week regimens in other real-world studies of LDV/SOF Table 2.1,2

LIMITATIONS

Members for whom viral load data is not available or who had undetectable viral load less than 12 weeks after treatment completion were not included (N=228). These members may account for additional cure rate data.

Pharmacy claims data was only available for claims billed to a MassHealth FFS or PCC plan. Medications billed to other payers or paid in cash are not included, and may affect for additional drug-drug interactions.

Data regarding history of failure on a previous HCV treatment or DAA agent were collected from the internal database of the MassHealth comprehensive HCV medication management program, and included disinfection of prior therapies because of adverse events, as well as relapse after completion of a full treatment course.

CONCLUSION

Treatment of HCV genotype 1 with LDV/SOF is associated with a high rate of SVR12 in one state’s Medicaid population, including treatment with 8 weeks of LDV/SOF in non-cirrhotic and treatment with a baseline HCV RNA <6 million IU/mL.

The clinical and demographic variables included in this study were not found to be predictors of treatment failure, as they were not associated with statistically significant differences in odds of failure to achieve SVR12. However, comorbidities were associated with lower odds of failure to achieve SVR12 in members receiving 24 weeks of LDV/SOF.

REFERENCES