Pan-Genotypic Hepatitis C Treatment With Glecaprevir/Pibrentasvir Achieves Greatest Improvements in Quality-Adjusted Life-Years and Lifetime Risk Reductions in Liver-Related Morbidity and Mortality vs Standards of Care: A Cost-Utility Analysis

Sammy Saab, Helene Parise, Suchin Virabhak, Scott Johnson, Brett Pinsky, Yuri Sanchez Gonzalez

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Presented at The American Association for the Study of Liver Diseases (AASLD) Congress, October 20–24, 2017, Washington, DC, USA

BACKGROUND

• HCV is a leading cause of chronic liver disease, cirrhosis, and hepatocellular carcinoma with approximately 6 million infected patients in the United States.

• Current standard of care (SOC) for treatment-naïve, GT 1–6 patients with viremia >100,000 IU/mL, is sofosbuvir/ledipasvir (SOF/LDV).

• Current guidelines recommend treating GT 1–6 HCV-infected patients with pan-genotypic direct-acting antiviral regimens.

• GT 2–3 patients have higher SVR, lower lifetime risk of liver-related death (LrD), and lower overall lifetime liver morbidity compared to GT 1–6 patients.

• GT 4–6 patients have lower SVR rates and greater relative risk of HCC compared to GT 1–6 patients.

OBJECTIVE

• To project the quality-adjusted life-years (QALYs), lifetime costs, and lifetime liver morbidity and mortality associated with pan-genotypic treatment with glecaprevir/pibrentasvir (G/P) compared to current standards of care (SOC; SOF/LDV) in treatment-naïve patients across all genotypes (GTs) and standard-of-care (SOC) strategies.

METHODS

• Model settings and structure: A Markov model with a lifetime time horizon and 2-month cycle length.

• Cohort: A cohort of treatment-naïve patients with chronic HCV across all GTs and cirrhosis status was simulated in the model.

• Transition probabilities: Transition probabilities were obtained from a US cohort study of patients treated with G/P in the US.

• Lifetime liver-related costs and costs of death from non-hepatic causes were estimated using a US perspective.

• Costs and utilities: Costs and utilities were estimated using a US perspective.

• Sensitivity analysis: A probabilistic sensitivity analysis (PSA) was conducted to evaluate the robustness of the findings.

RESULTS

Table 1: Patient Outcomes and Cost-effectiveness of Treatment With G/P vs Standards of Care

<table>
<thead>
<tr>
<th>Strategy</th>
<th>QALYs</th>
<th>LYG</th>
<th>LE at baseline age</th>
<th>Breakdown of total costs</th>
<th>Cost-effectiveness analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategy 1:</td>
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<td>Strategy 2:</td>
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</table>

• Treatment with G/P was the dominant option, resulting in an increase in lifetime QALYs (18.2) compared to current standards of care in an assessment of pan-genotypic treatment with G/P.

• The model compared pan-genotypic treatment with G/P to current standards of care (SOC; SOF/LDV) in treatment-naïve patients across all genotypes (GTs) and standard-of-care (SOC) strategies.

CONCLUSIONS

• Compared with current standards of care, pan-genotypic treatment with G/P offers the most favorable improvements in quality-adjusted survival, costs, and lifetime risk reductions in liver-related morbidity and mortality.

DISCLOSURES

• This analysis was funded by AbbVie Inc., and paid for by AbbVie Inc. AbbVie Inc. participated in the development of the model and maintained control over the final content.

• The authors are employees of Medicus Economics, LLC. Medicus Economics, LLC, received consulting fees for this analysis from AbbVie Inc., and paid for by AbbVie Inc.

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ACKNOWLEDGMENT

Follow-up support for postdoc development was provided by AbbVie Inc.; AbbVie Inc. also funded the preparation of the final study, model development, and maintenance.

REFERENCES

Among Cohort 1, treatment with G/P resulted in statistically significant PTW4 (p=0.0001). Not all patients in the current analysis received treatment as per the current approved USFDA label.

Overall SVR12 rate of 98% in over 2000 patients in Phase 3 studies.

The beneficial effects of HCV treatment on EHM outcomes were maintained in the current study for HCV patients treated with PIB. Treatment of HCV with interferon-based triple therapy has been associated with increased risk of end stage renal disease (ESRD) and higher efficacy of direct acting drugs (DAA) could avoid the need for renally sparing medications.

The majority of patients in Cohort 2 were on boceprevir or telaprevir with PIB. With the depleting pool of warehoused cirrhotic patients and higher efficacy of direct acting drugs (DAA), we could avoid the need for renally sparing medications.

DISCUSSION

Population

For the first time, a large number of treated cirrhotic patients and higher efficacy of previous generation DAA, the new pool of transplant candidates is likely to be the Treatment

benefits on renal outcomes were also observed in treatment-naive patients with ESRD, for this population receiving 8 weeks treatment.

The stable eGFR function shown during and post treatment was inferred based on prior published literature and further analyses of kidney function in cirrhosis patients.

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DISCUSSION

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For the first time, a large number of treated cirrh
Chronic kidney disease and hepatitis C mutually advance liver and renal disease progression: real-world evidence from the United States

Tram Tran, Yurie Sanchez Gonzalez, Oscar Hayes, Steven E. Marx

*Cedars-Sinai Medical Center, Los Angeles, CA; Abbvie Inc., North Chicago, IL

Presented at The American Association for the Study of Liver Diseases (AASLD) Congress, October 20–24, 2017, Washington, DC, USA

BACKGROUND

- A comprehensive review of recent epidemiologic literature, the global prevalence of chronic kidney disease (CKD) is estimated to be 1.1% (5-14%), corresponding to approximately 304 (204-424) million people interested, resulting in substantial burden for society and healthcare systems.
- End-stage renal disease (ESRD) management has been associated with chronic kidney disease (CKD) in common and varied, frequently increasing the burden of CKD.
- Among a broad range of ERD, CKD has been associated with increased incidence of chronic kidney disease (CVD).
- Evidence suggests that patients comorbid with both CKD-related liver disease and CKD may have increased morbidity and mortality.
- However, there is limited evidence on the extent to which having HCV and CKD may have mutually advanced time to renal and liver disease progression.

OBJECTIVE

- To assess how CKD affects liver disease progression in patients with HCV, and how HCV affects renal disease progression in patients with CKD.

METHODS

- Large de-identified database of physician- and patient-level data including medical claims, pharmacy claims, lab results, and administrative data in the United States from 2006 to present day.
- Database covers 16 million lives annually and was updated annually/quarterly.

DATA ANALYSIS

- Disease progression was analyzed using Kaplan-Meier plots for up to 10 years post-index, between 2006–2016.

STATISTICAL ANALYSIS

- Multivariable, random-effect, and regression with negative-binomial distributions were used for statistical analysis of categorical, continuous, and count variables, respectively.

STUDY DESIGN: LIVER DISEASE PROGRESSION (FIGURE 1)

- To assess the influence of CKD on liver disease progression, a cohort of patients with HCV was identified.
- Index date: date of first CKD diagnosis between 2006–2016.
- The subgroup of patients with a CKD diagnosis at or prior to HCV was compared to HCV patients without a CKD diagnosis.

STUDY DESIGN: RENAL DISEASE PROGRESSION (FIGURE 2)

- To assess the influence of CKD on renal disease progression, a cohort of patients with HCV was identified.
- Index date: date of first CKD diagnosis between 2006–2016.
- The subgroup of patients with a CKD diagnosis at or prior to HCV was compared to CKD patients without HCV a diagnosis.

RESULTS

LIVER PROGRESSION COHORT (TABLE 1)

- A total of 7,656 patients with a diagnosis of HCV between 2006–2016 were identified.
- Of these, 1,586 (21.5%) had a pre-index CKD diagnosis of CKD within 1 year prior to HCV.
- A significantly higher percentage of patients with HCV demonstrated annualized eGFR decrease of ≥4 mL/min/1.73 m²/year post-index.

RENAL PROGRESSION COHORT (TABLE 2)

- A total of 4,758 patients with a diagnosis of HCV between 2006–2016 eligible for an annualized eGFR decrease were identified.
- A significantly higher percentage of CKD patients with HCV demonstrated renal disease progression as compared to HCV-only patients (p<0.001).

DISCUSSION

- Among a cohort of HCV patients, a significantly greater percentage of those with concomitant CKD demonstrated liver fibrosis progression within 10 years compared with HCV patients without CKD.
- A significantly higher percentage of those with concomitant CKD demonstrated renal disease progression compared with patients without HD.
- Differences in disease progression between patients with or without the respective comorbidity in each cohort were apparent.
- These results suggest that early identification and treatment of chronic hepatic fibrosis (HCV) could lead to mutual health benefits for liver and renal disease.

LIMITATIONS

- This analysis was based on claims data, which are subject to several limitations as the primary purpose of claims data is reimbursement, not research.

CONCLUSIONS

- Liver fibrosis and CKD are worsened when both are present as comorbidities compared with when only one condition is present.
- Early identification and treatment of chronic hepatic fibrosis (HCV) could lead to mutual health benefits for liver and renal disease.

REFERENCES

6. Fishawack Facilitate, and funded by AbbVie.
8. Editorial support for poster development was provided by Rebecca Wolfe, of MCRS Consulting, Ltd.

ACKNOWLEDGMENT

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DISCLOSURES

Design and study conduct for the study was approved by AbbVie Inc. AbbVie and Fishawack provided funding for this congress presentation. All authors participated in the planning, design, and conduct of the study. Al and were responsible for the final content. Fishawack provided consulting, advisory/speaker fees, and research grants from AbbVie, Bristol-Myers Squibb, and Gilead.

Note: This is a summary of the full manuscript. MCRS & X gathers are employees of AbbVie and may own stocks and/or options of the company.
Assessing Patient Preferences for and Relative Importance of Features of New Direct Acting Antiviral (DAA) Treatments for Chronic Hepatitis C Virus (HCV) Infections

Tania M. Welzel1, Min Yang2, Gautam Sajeey, Brett Pinsky1, Darshan Mehta3,4, Yanjun Bao3, Eric Q. Wu, Yaozhu I. Chen3

1 W Goethe University, Frankfurt, Germany; 2Analysis Group, Inc., Boston, Massachusetts, United States; 3AbbVie Inc., North Chicago, Illinois, United States; 4Scheffler Center for Health Policy and Economics, University of Southern California, Los Angeles, California, United States

Presented at the American Association for the Study of Liver Diseases (AASLD) Congress; October 20–24, 2017; Washington, DC, USA

Table 1. Features and levels

<table>
<thead>
<tr>
<th>Feature</th>
<th>Levels</th>
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<tbody>
<tr>
<td>Treatment duration</td>
<td>16 weeks, 8 weeks</td>
</tr>
<tr>
<td>Once-daily tablet count and packaging</td>
<td>1 tablet from a press-on blister pack, 2 tablet in a single-dose blister pack</td>
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<tr>
<td>Cure rate</td>
<td>100% chance to be cured (standardized)</td>
</tr>
<tr>
<td>Follow-up visit during treatment</td>
<td>2 additional office visits (no in-person visit, 1 visit for post-treatment evaluation)</td>
</tr>
<tr>
<td>Modification of concurrent statin use</td>
<td>temporarily reduce dose or timing, temporarily reduce or modify timing of PPI use, modification of PPI use</td>
</tr>
<tr>
<td>Risk of side effects</td>
<td>Risk of nausea 5%; 15%; 25%; Risk of headache 5%; 15%; 25%; Risk of diarrhea 5%; 15%; 25%; Risk of adverse events 5%; 15%; 25%</td>
</tr>
<tr>
<td>Preference weight</td>
<td>Preference weight</td>
</tr>
</tbody>
</table>

Figure 1. An example choice card

Figure 2. Comparison of treatment features to patients (overall population)

Figure 3. Importance of treatment features to patients (by treatment experience subgroups)

Table 2. Participants’ characteristics (N=328)

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>N (%)</th>
</tr>
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<tbody>
<tr>
<td>Country/region</td>
<td></td>
</tr>
<tr>
<td>EU5</td>
<td>211 (64.3)</td>
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<td>US</td>
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<tr>
<td>Men</td>
<td>192 (58.5)</td>
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<td>136 (41.5)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>Completed 6–12 years of education</td>
<td>103 (31.4)</td>
</tr>
<tr>
<td>Decline to answer</td>
<td>4 (1.2)</td>
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<tr>
<td>Injectable recreational drug use, n (%)</td>
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<tr>
<td>No modification to a statin</td>
<td>214 (65.2)</td>
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<tr>
<td>Temporary reduce dose or modify timing</td>
<td>114 (34.8)</td>
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<tr>
<td>Modification of concurrent use of PPIs</td>
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<td>No modification to a PPI</td>
<td>254 (77.2)</td>
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<tr>
<td>Temporary reduce or modify timing of PPI use</td>
<td>74 (22.8)</td>
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<tr>
<td>Younger age</td>
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<tr>
<td>HCV disease and treatment history</td>
<td></td>
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<tr>
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<tr>
<td>Risk of headache</td>
<td></td>
</tr>
<tr>
<td>≥5%</td>
<td>165 (50.1)</td>
</tr>
<tr>
<td>&lt;5%</td>
<td>163 (49.9)</td>
</tr>
<tr>
<td>Risk of side effects</td>
<td></td>
</tr>
<tr>
<td>≥25%</td>
<td>163 (49.9)</td>
</tr>
<tr>
<td>&lt;25%</td>
<td>165 (50.1)</td>
</tr>
</tbody>
</table>

DISCUSSION/LIMITATIONS

• Given the overall high efficacy of new DAA, HCV patients’ preferences for therapy may differ based on treatment features other than efficacy/effectiveness
• Less disruption to a patient’s life (such as no modification in PPi use, lower risk of adverse events) and added convenience (such as shorter treatment duration, fewer office visits during treatment) seem to be important from HCV patients’ perspective
• Improved understanding of patients’ preferences for features of new DAAs can help facilitate communication with patients and inform other key stakeholders such as physicians and payers to potentially improve treatment outcomes

CONCLUSIONS

• Preferences for monitoring differed in TE IFN-only patients compared with TN and IFN-free patients, which should be considered when planning use of DAA in these patients
• Preferences were generally similar between US and EU5 patients, although US patients preferred less monitoring burden during treatment
• Findings from this online, panel-based patient survey may not be generalizable to the broader population of HCV patients
• Recall bias of disease and treatment-related medical history may be present
• Patient preferences for hypothetical HCV therapies may not represent their preferences for HCV treatments received in the real world

REFERENCES


Acknowledgment

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An Analysis of Potential Elimination Strategies for Hepatitis C Using a Budget Optimization Model for the UK

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**Background**

- The introduction of highly effective oral direct acting antivirals (DAAs) offers countries an opportunity to care hepatitis C virus (HCV) and meet the World Health Organization (WHO) targets for eliminating viral hepatitis as a public health threat in the population by 2030.
- Access to DAA treatment in the UK is increasing and no longer restricted to the most severe cases but there remains a large percentage of patients estimated at 50% who remain undiagnosed and therefore making elimination a challenge.
- These patients will continue to have a significant impact on the future burden of the disease.

**Objectives**

- To understand the optimal use of current HCV budget allocations for the United Kingdom (UK) based on liver fibrosis stage and the impact on the 2018 WHO elimination targets.
- To assess what impact greater investment in treatment and screening will have on the current burden and speed of elimination of HCV in the UK.

**Methods**

**Model Design**

- A sequential multi-cohort, health state transition Markov model (Figure 1) was designed to assess the clinical and economic outcomes for the UK HCV population from 2017 until 2030.
- The model used annual cycles for the eligible HCV population diagnosed 4,603.
- The model assumed that F2 fibrosis stage patients prioritizing the most advanced cases (F4→F0) or treating patients with F4 first (F4→F0) would achieve the most favorable patient outcomes.
- The model used annual cycles for the eligible HCV population diagnosed 4,603.
- The burden from the 16,530 undiagnosed prevalent patients is reduced.
- SVR inputs may differ from rates observed in real-world settings.
- Steps To Elimination By Increasing Diagnosis Rate and Budget (Figure 2 and 3)
- Under current rates of diagnosis (10%) elimination amongst diagnosed HCV patients will be achieved by 2025 but the 112,551 undiagnosed patients will continue to pose a high healthcare burden.
- Incremental analysis of cost effectiveness shows savings made in liver related costs if costs for extra hepatic manifestations are included savings are £914.
- If costs for extra hepatic manifestations are included savings are £914.
- To assess what impact greater investment in treatment and screening will have on the current burden and speed of elimination of HCV in the UK.

**Results**

- Optimal treatment: stepwise strategy F4→F0 (Strategy 12)
- Among all budget feasible treatment options, the stepwise strategy to sequential treatment of fibrosis stages prioritizing the most advanced cases (F4→F0) met all feasible liver outcomes and minimized adverse liver outcomes by 2030 (Table 2).
- It contrasts a strategy of sequential treatment to stages F3→F4 (which historically was observed in UK) predicted 100,000 fewer SVR cases and an increase of 133,614; £6,461,273; and 146; 083 non-cancer deaths.

**Discussion**

- The sequential treatment of all fibrosis stages, prioritizing the most advanced cases, achieves the most favorable patient outcomes.
- Restricting treatment to most severe patients while reducing treatment costs yields higher adverse outcomes and consequently higher medical costs in the future.
- Under current rates of diagnosis (10%) elimination amongst diagnosed HCV patients will be achieved by 2025 but undiagnosed patients will continue to pose a high healthcare burden.
- Improving diagnosis rates remains central to achieve elimination and requires better screening strategies.

**Acknowledgements**

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**References**

2. Anonymous. 2015; 230 million and the current diagnosis rate of 50%.
5. Anonymous. 2015; 3. This paper is free available in PubMed with the following doi: 10.1111/1448-5585.12304.
Hepatitis C virus is the most common cause of chronic liver disease.

A total of 229 8 week treated patients and 103 12 week treated patients were included in the study. By the end of treatment period, all GLE/PIB treated patients experienced statistically significant improvements in QoL compared to baseline.

The items are scored on a 7 point scale with scores ranging from 0 to 6.

Baseline values on EQ 5D were in line with the values observed in Japanese general population (HUI > 0.9) at baseline with majority of population reporting perfect health (EQ 5D HUI > 0.9).

The study sampled patients enrolled in clinical trials, therefore results may not be generalizable to treatment-naive patients.

Higher scores indicate a better health-related quality of life (HRQoL).

The proportion of patients reporting perfect health increased by end of treatment irrespective of patient population considered. This was maintained during the post treatment period.

The proportion of patients reporting perfect health at each time point was consistently higher as compared to general population norm of 60%.

Higher scores indicate greater unobserved health.