Hepatitis C virus (HCV) is the leading cause of advanced liver disease and is estimated to cost over $7 trillion annually in the United States (US).

We conducted a secondary analysis of HCV patients initiating dual or triple oral direct-acting antiviral therapy between January 1, 2014 and March 12, 2018 at four US institutions with a clinical characterization-driven treatment model.

The best performing model (≥40%) had significantly better predictive ability than the ≥50% (p = 0.03) and ≥80% models (p = 0.02) in the validation set, but highlighted baseline HCV patient factors associated with failure to achieve measured SVR.

Overall SVR rate = 86.1% (95% CI = 84.1%, 88.0%)

The best performing model (≥40%) had significantly better predictive ability than the ≥50% (p = 0.03) and ≥80% models (p = 0.02) in the validation set, but poor discriminative ability.

Most likely predictors of failure to achieve measured SVR were older age, presence of hepatocellular carcinoma, and private versus public insurance.

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• We conducted a secondary analysis of HCV patients initiating dual or triple oral direct-acting antiviral therapy between January 1, 2014 and March 12, 2018 at four US institutions with a clinical characterization-driven treatment model.

• University of Illinois Hospital and Health Sciences System (n = 862)

• Vanderbilt University Medical Center (n = 296)

• Temple University Hospital (n = 146)

• Creighton University (n = 54)

• Failure to achieve measured SVR was defined by three independent treatment outcomes: HCV RNA detectable, lost to follow-up, and early treatment discontinuation.

• Twenty baseline (collected before treatment initiation) patient-level candidate predictor variables were selected or priori based on pharmacists’ clinical experience.

• A 1st variable elimination: removed variables with collinearity or prevalence <3% in total dataset

• 2nd variable elimination: removed variables with collinearity or prevalence <3% in total dataset

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• In the derivation set, separate prediction models were developed from 100 bootstrap samples (n = 837) using stepwise logistic regression clustered by institution.

• From the 100 models, variables were ranked by frequency of selection as predictors.

• Four separate prediction models were developed using variables that were selected in ≥80%, ≥75%, and ≥70% of bootstrap samples and using all candidate predictors remaining after the 2nd variable elimination phase.

• In the validation set, predictive performance was compared across the 4 prediction models using area under the receiver operating characteristic curve (AUC).

RESULTS

• Overall SVR rate = 86.1% (95% CI = 84.1%, 88.0%)

• The best performing model (≥40%) had significantly better predictive ability than the ≥50% (p = 0.03) and ≥80% models (p = 0.02) in the validation set, but poor discriminative ability.

• Most likely predictors of failure to achieve measured SVR were older age, presence of hepatocellular carcinoma, and private versus public insurance.

REFERENCES


3. History of hepatocellular carcinoma (HCC)

4. Psychiatric illness

5. Post-transplant

6. Obesity

7. Post-transplant immunosuppression agents

8. Opioid replacement agents

9. HIV-infected

10. Cirrhosis

11. History of alcohol use

12. 80% of bootstrap models

13. 50% of bootstrap models

14. All candidate variables

LIMITATIONS

• Small sample size for split sample approach:

• Reduced power and increased bias and variability

• Only assessed main effects, not interactions

• Unable to analyze patients by specific treatment outcome group (HCV RNA detected, lost to follow-up, and discontinuation treated).

CONCLUSION

• This study did not result in a highly predictive model, but highlighted baseline HCV patient factors associated with failure to achieve measured SVR.

• Prediction of failure to achieve measured SVR may facilitate development of data-driven clinical tools to identify patients who would benefit from interventions to improve SVR rates.

• Discontinued quality of life

• HCV-related mortality

• Continued transmission of HCV

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DRI Services, Inc. provided funding data collection and analysis for the original study.Investigators collected data and analyzed results without any input from the sponsor.