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Medication Adherence to Direct Acting Anti-viral Agents among Hepatitis C Virus Infected Patients in the United States 2017-2019

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BACKGROUND

- Around 3.6 million individuals in the United States harbor hepatitis C virus (HCV) antibodies, of which 2.7 million are presently infected (1) and is the primary cause of liver transplantation and hepatocellular cancer (HCC) in the United States (2).
- Historically, treatment of HCV involved weekly injections of pegylated interferon plus ribavirin for 48 weeks, yielding SVRs of 45–50%. The advent of direct-acting antiviral agents (DAAs) in 2011, combined with pegylated interferon and ribavirin, elevated SVR rates to 67–73% in treatment-naive genotype 1 patients.
- Patients with chronic hepatitis C must adhere to the complete treatment regimen to maximize antiviral therapy efficacy (3, 4). However, limited data on treatment adherence and discontinuation of DAAs in real-world clinical practice are available.
- Understanding the real-world utilization of DAAs and assessing adherence is crucial for developing strategies to enhance regimen efficacy and identifying patients at risk for adherence-related treatment failure.

OBJECTIVE

The primary aim of this study was to identify the adherence rate to DAAs among HCV-infected patients. The secondary objective was to evaluate predictors of adherence to DAAs.

METHODS

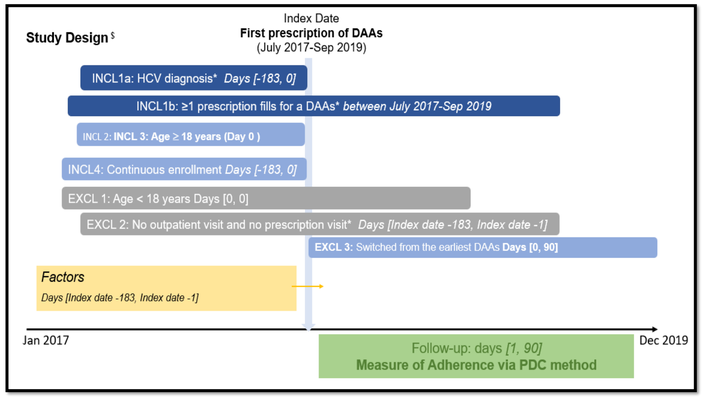
Data sources:

- This retrospective cohort study utilized the Merative MarketScan Commercial databases from January 2017 to December 2019.

Inclusion Criteria

- Patients with diagnosed HCV infection were identified utilizing specific International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes [B18.2, B19.20, B19.21, Z22.52].
- Eligible HCV patients were required to have either one inpatient chronic HCV diagnosis or two separate outpatient diagnoses of HCV within a one-year period.

METHODS



INCL=inclusion, EXCL= exclusion; HCV= hepatitis C virus infection, DAAs = Direct Acting anti-viral agents
$ ISPE structured template for planning and reporting on the implementation of real-world evidence study

Outcome:

- Our primary endpoint was the adherence to DAAs over a 3-month follow-up, quantified as a binary variable. An adherence level with a Proportion of Days Covered (PDC) ≥0.80 was categorized as adherent, while PDC < 0.8 was considered non-adherent.

Conceptual Framework and Covariates:

- The conceptual framework and covariates were determined based on the Anderson Behavioral Model, which posits that healthcare utilization is influenced by predisposing, enabling, and need factors (20).

Analyses:

- Descriptive statistics (mean for continuous variables and percentage for categorical variables) and hypothesis testing for group differences using t-tests and Chi-square tests were used.
- Baseline and clinical characteristics were compared between the adherent vs. non-adherent group. A multivariable logistic regression model was then executed to identify predictors for DAAs, controlling for sociodemographic and clinical characteristics.
- Analysis was performed by using SAS version 9.4 adhering to an a priori significance level of 0.05.

RESULTS

Table 1. Basic sociodemographic and clinical characteristics of direct-acting antiviral (DAA) among HCV-infected patients and Multivariate analysis by adherence level

		Total	Adherent Group (n= 2,853, 68.04%)	Non-Adherent Group (n= 1,340, 31.95%)	P-value	Adjusted Odds Ratio	95% Confidence Interval		P-value
PREDISPOSING FACTORS									
Age									
	18 Years to 34 Years	611	353 (12.37)	258 (19.25)	<.0001	Reference	---	---	---
	35 Years to 44 Years	372	215 (7.54)	157 (11.72)		0.952	0.723	1.255	0.1043
	45 Years to 54 Years	989	679 (23.8)	310 (23.13)		1.214	0.968	1.524	0.1392
	55 Years to 64 Years	2221	1606 (56.29)	615 (45.9)		1.268	1.028	1.565	**0.0153**
Sex	Male	2523	1721 (60.32)	802 (59.85)	0.7711	Reference	---	---	---
	Female	1670	1132 (39.68)	538 (40.15)		1.122	0.973	1.294	0.1127
Region	Northeast	651	440 (15.42)	211 (15.75)	0.1255	Reference	---	---	---
	North Central	709	488 (17.1)	221 (16.49)		1.098	0.86	1.401	0.765
	South	2177	1506 (52.79)	671 (50.07)		0.946	0.773	1.158	0.5087
	West	645	411 (14.41)	234 (17.46)		1.019	0.794	1.308	0.8723
Metropolitan statistical area	No	496	352 (12.34)	144 (10.75)	0.1367	Reference	---	---	---
	Yes	3697	2501 (87.66)	1196 (89.25)		0.848	0.681	1.056	0.1401
ENABLING FACTORS									
Employment	Other	849	599 (21)	250 (18.66)	0.0064	Reference	---	---	---
	Active	3025	2018 (70.73)	1007 (75.15)		0.947	0.786	1.14	0.2391
	Retire	319	236 (8.27)	83 (6.19)		1.11	0.807	1.527	0.3687
***Plan Type**	Others†	2034	1369 (47.98)	665 (49.63)	0.3211	Reference	---	---	---
	PPO	2159	1484 (52.02)	675 (50.37)		0.997	0.863	1.153	0.9728
Physician specialty coding flag	< 70% Physician Records with specialty	79	45 (1.58)	34 (2.54)	0.033	Reference	---	---	---
	≥70%	4114	2808 (98.42)	1306 (97.46)		1.621	0.977	2.692	0.0617
NEED FACTORS									
Comorbidities	No	2056	1329 (46.58)	727 (54.25)	<.0001	Reference	---	---	---
	1 Comorbidity	1518	1051 (36.84)	467 (34.85)		1.48	1.27	1.724	0.7889
	≥ 2 Comorbidities	619	473 (16.58)	146 (10.9)		2.286	1.826	2.861	**<.0001**
Compensated Cirrhosis	No	3937	2688 (94.22)	1249 (93.21)	0.2038	Reference	---	---	---
	Yes	256	165 (5.78)	91 (6.79)		0.987	0.732	1.33	0.9308
Decompensated Cirrhosis	No	4009	2725 (95.51)	1284 (95.82)	0.6504	Reference	---	---	---
	Yes	184	128 (4.49)	56 (4.18)		1.112	0.779	1.589	0.5578
Diabetes mellitus	No	3572	2341 (82.05)	1231 (91.87)	<.0001	Reference	---	---	---
	Yes	621	512 (17.95)	109 (8.13)		1.804	1.43	2.275	**<.0001**
HIV Infection	No	4070	2744 (96.18)	1326 (98.96)	<.0001	Reference	---	---	---
	Yes	123	109 (3.82)	14 (1.04)		6.307	3.541	11.231	**<.0001**
Hypertension	No	2277	1284 (45.01)	993 (74.1)	<.0001	Reference	---	---	---
	Yes	1916	1569 (54.99)	347 (25.9)		3.351	2.859	3.927	**<.0001**
Hospital admissions	≥1 Hospitalization	485	356 (12.48)	129 (9.63)	0.0071	0.899	0.423	1.909	0.781
Emergency department visits	≥1 ED visit	830	583 (20.43)	247 (18.43)	0.1293	1.097	0.626	1.921	0.746

CONCLUSIONS

About two-thirds of the HCV-infected patients had optimal medication adherence, with comorbidities playing a critical role in medication adherence. Concerted efforts are needed to increase DAA adherence with an opportunity to utilize positive triggers like comorbidities to lower patients' risk of developing resistance to future treatments.