Hepatitis C Virus Testing, Prevalence, and Treatment in a Large Cohort of Treatment-Naïve, HIV-Positive Individuals

Douglas Dieterich[1], Cassidy Henegar[2], Jennifer Fusco[2], and Phil Lackey[3]

[1]Mt. Sinai Healthcare System, New York, NY; [2]Epividian, Inc., Durham, NC; [3]Carolinas Healthcare System, Charlotte, NC

OPERA® The Longitudinal Cohort

Contact Information:
4819 Emperor Blvd., Suite 400 Durham, NC 27703
P: 919-825-3457 F: 919-313-4505
Email: jennifer.fusco@epividian.com

BACKGROUND

HIV populations are at greater risk for HCV due to their shared modes of transmission.[1] Among those with HCV, HIV-coinfection is associated with higher risk of fibrosis, hepatic decompensation and cirrhosis.[2] Treatment of HCV in HIV/HCV coinfected patients has been revolutionized by direct acting antivirals (DAAs), with response and cure rates equivalent to HCV mono-infected patients.[3]

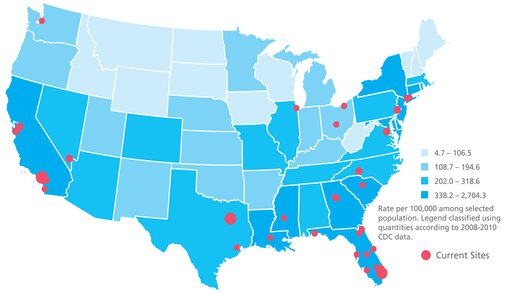
OBJECTIVE:

Evaluate HCV testing and treatment patterns among HIV patients to improve identification and outcomes of co-infected patients.

METHODS

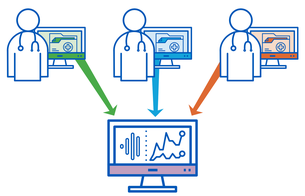
- This analysis has been updated with an additional 6 months of data since the abstract was drafted
- Using the Observational Pharmaco-Epidemiology Research and Analysis (OPERA) database, a collaboration of caregivers at 79 clinics in 15 states [Figure 1], HIV+ individuals initiating HIV antiretroviral therapy (ART) for the first time were identified. [Figure 1]

Figure 1: U.S. Map of OPERA HIV+ Population & CDC (2010) State-by-State Estimates



- Prospectively collected data related to HIV and HCV data (labs, diagnoses, and treatments) were extracted from electronic health records and aggregated into a national research database. [Figure 2]

Figure 2: Individual electronic medical record databases are anonymized and aggregated to create OPERA

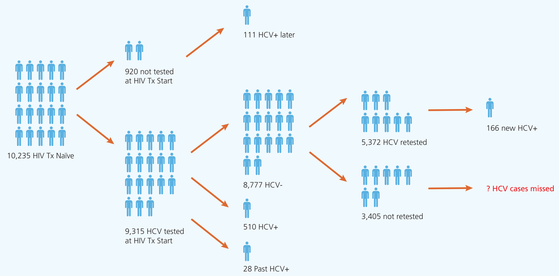


- Patients were restricted to those initiating HIV ART for the first time between 1/1/2007 and 10/1/2015 to reflect the modern era of HIV therapy and to allow all patients to have a minimum of 12 months of follow up. Patients were followed until data freeze (10/1/2016), death, or loss to follow-up.

RESULTS

- Out of 10,235 HIV+ treatment naïve patients, 91% were evaluated for HCV prior to ART initiation; 8,777 (94%) were HCV antibody-negative (Ab-), 510 (5%) were HCV+ (by viral load, diagnosis or treatment record), and 28 (0.3%) had a history of resolved HCV at baseline. [Figure 3]

Figure 3: HCV Testing in the HIV+ Population of OPERA



- After starting ART, 5,372 (61%) of the 8,777 HCV Ab- patients were reevaluated for HCV, resulting in 166 (2%) new HCV diagnoses and 111 (1%) new cases of HCV in patients not tested prior to initiating HIV therapy.
- HIV+/HCV+ patients were significantly older, more likely to be female and have had an AIDS-defining illness, less likely to be MSM or Hispanic, and had a lower CD4 count. [Table 1]

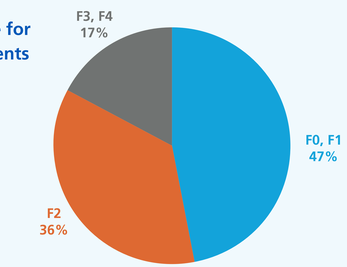
Table 1: Patient Characteristics at Baseline

	HIV+ N= 8777	HIV+/HCV+ N= 510	p-value
Age (Median, IQR)	33.7 (26,5, 43.4)	46.6 (38.6, 52.4)	**<0.0001**
Gender, Male	7597 (86.6%)	395 (77.6%)	**<0.0001**
Risk of Infection, MSM*	5127 (58.4%)	201 (39.4%)	**<0.0001**
Race, African American	3489 (39.8%)	200 (39.2%)	0.81
Ethnicity, Hispanic	2281 (26.0%)	89 (17.5%)	**<0.0001**
Log^{10} HIV-1 Viral Load (Median, IQR)	4.7 (4.2, 5.1)	4.7 (4.2, 5.1)	0.4188
CD4 Count (Median, IQR)	334 (194, 483)	273 (154, 442)	**0.0002**
AIDS Defining Event at Baseline	611 (7.0%)	49 (9.6%)	**0.0237**
History of Syphilis at Baseline	1940 (22.1%)	111 (21.8%)	0.8578

* MSM: men who have sex with men

- Of the 510 HIV/HCV co-infected patients, over half (n=259) had a FIB-4 of F2 or greater at baseline; 16.5% (n=81) already had a FIB-4 score of F3 or F4. [Figure 4] Genotypes were available for 322 (63%) cases (1a: 69%, 1b: 16%, 2: 7%, 3: 7%, 4: 1%).

Figure 4: Fibrosis Scores at Baseline for HIV/HCV Co-Infected Patients



- In addition to liver fibrosis, HIV/HCV co-infected patients suffer from more comorbid conditions at the initiation of care. Most notable, endocrine disorders, mental health conditions, hypertension, and substance abuse. [Table 2]

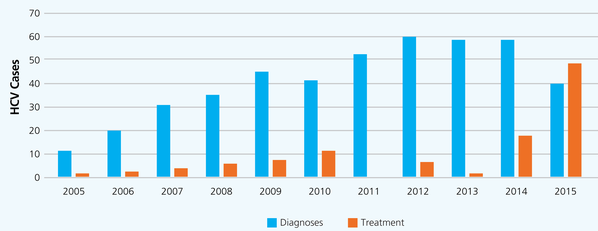
Table 2: Comorbid Conditions at Baseline

Characteristic	HIV+ N= 8777	HIV+/HCV+ N= 510	p-value
Any Comorbid Condition*	3771 (43.0%)	365 (71.6%)	**<0.0001**
CVD Conditions	200 (2.3%)	25 (4.9%)	**0.0002**
Invasive Cancer	145 (1.7%)	15 (2.9%)	**0.0296**
Endocrine Disorders	1111 (12.7%)	86 (16.9%)	**0.0059**
Mental Health Conditions	1146 (13.1%)	133 (26.1%)	**<0.0001**
Peripheral Neuropathy	196 (2.2%)	31 (6.1%)	**<0.0001**
Renal Disease	41 (0.5%)	10 (2.0%)	**<0.0001**
Hypertension	1129 (12.9%)	113 (22.2%)	**<0.0001**
Substance Abuse	1207 (13.8%)	163 (32.0%)	**<0.0001**

* Excluding Hepatitis

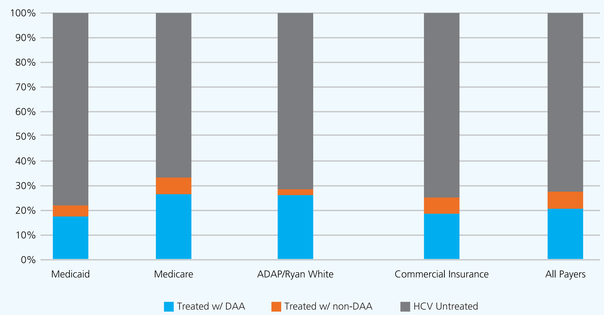
- Only 27% (n=138) were ever treated for HCV, most commonly after HIV ART initiation (n=124, 90%) and in the DAA-era (n=101, 73%). Median time between HCV diagnosis and HCV treatment was 30 months (IQR: 12, 66). [Figure 5]
- Overall, 76% of the treated cases received DAA-based therapy, including 99% of cases treated in 2014 or later.

Figure 5: Diagnosed and Treated HCV Cases by Year



- Co-infected patients insured with Medicaid or commercial plans were the least likely to receive DAA HCV treatment (18% and 19%, respectively). [Figure 6]

Figure 6: Proportion of HIV/HCV Patients Treated for HCV by Payer Type



CONCLUSIONS

- Most patients in this treatment-naïve HIV population were evaluated for HCV, however only about a quarter of the confirmed cases received treatment.
- In addition to fibrosis, co-infected patients had a significant burden of comorbid conditions at baseline.
- Among the treated, most experienced a delay of two or more years between HCV diagnosis and treatment initiation. With increased availability of effective DAAs, more patients are receiving therapy.
- Given the importance of controlling HCV disease progression in coinfected patients, and the existence of modern, effective therapies, greater effort should be made to offer HCV treatment to all coinfected patients, and to continue monitoring for HCV infection among HIV mono-infected patients beyond baseline.

KEY FINDING:

Increased vigilance is needed in retesting HIV patients after they initiate HIV therapy to identify new HCV infections.

REFERENCES

1. CDC: Sexually Transmitted Disease Treatment Guidelines 2015. MMWR 2015; 64 (No.3)
2. Rotman Y, Liang TJ. Coinfection with Hepatitis C Virus and Human Immunodeficiency Virus: Virological, Immunological, and Clinical Outcomes. J. Virol. August 2009; 83 (15): 7366-7374.
3. Rockstroh JK, Bhagani S. Managing HIV/hepatitis C co-infection in the era of direct acting antivirals. BMC Med 2013; 11: 234.

ACKNOWLEDGEMENTS

This research would not be possible without the generosity of the OPERA HIV caregivers and their patients sharing their experiences. Additionally, we are grateful for the following individuals: Gregory Fusco MD MPH (Advisory Board coordination), Robin Beckerman (SAS programming), Ted Ising (Database Arch & Mgmt), Bernie Stooks (Database Mgmt), Judy Johnson (Med Terminology Classification), Rodney Mood (Site Support & Data Analyst), Elizabeth Yancy (Data Analyst), Jeff Briney (Programming QA)

DISCLOSURES

None

Epividian®