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Hepatitis C treatment uptake and response among HIV/HCV-coinfected patients in a large integrated healthcare system

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Abstract

U.S. guidelines recommend that patients coinfected with HIV and hepatitis C virus (HCV) be prioritized for HCV treatment with direct-acting antiviral agents (DAAs), but the high cost of DAAs may contribute to disparities in treatment uptake and outcomes. We evaluated DAA initiation and effectiveness in HIV/HCV-coinfected patients in a U.S.-based healthcare system during October 2014–December 2017. Of 462 HIV/HCV-coinfected patients, 276 initiated DAAs (70% cumulative proportion treated over 3 years). Lower likelihood of DAA initiation was observed among patients with Medicare (government-sponsored insurance) vs. commercial

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Sharing of research materials: The analytical datasets from this project include patient-level data from the Kaiser Permanente Northern California (KPNC) electronic medical record, including demographics, diagnoses, procedures, and composite variables developed from multiple EHR sources. In our experience, given the complexity of this data, active partnerships with researchers external to KPNC will facilitate more productive collaborations that will effectively leverage the proposed dataset. External investigators can contact the corresponding author to initiate a request for study data to support new study proposals or manuscripts.

insurance (aRR=0.62, 95% CI=0.46-0.84), patients with drug abuse diagnoses (aRR=0.72, 95% CI=0.54-0.97), patients with CD4 count <200 vs. 500 (aRR=0.45, 95% CI=0.23-0.91) and patients without prior HCV treatment (aRR=0.68, 95% CI=0.48-0.97). There were no significant differences in DAA initiation by age, sex, race/ethnicity, socioeconomic status, HIV-transmission risk, alcohol use, smoking, fibrosis level, HIV RNA levels, ART use, hepatitis B infection, or number of outpatient visits. 95% of patients achieved SVR. We found little evidence of sociodemographic disparities in DAA initiation among HIV/HCV-coinfected patients, and SVR rates were high. Efforts are needed to increase DAA uptake among coinfecting Medicare enrollees, patients with drug abuse diagnoses, patients with low CD4 count, and patients receiving first-time HCV treatment.

INTRODUCTION

An estimated one-third of people living with human immunodeficiency virus (HIV) infection are coinfecting with hepatitis C virus (HCV).(1) Prioritizing HIV/HCV-coinfected patients for HCV treatment, as recommended by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America,(2) would substantially reduce liver-related morbidity and mortality. However, HCV treatment uptake has historically been low in this population for multiple reasons, including concerns about drug interactions with antiretroviral therapy (ART), competing medical priorities, ongoing substance use, anticipated poor tolerance of side effects and limited effectiveness of interferon-containing treatment regimens.(1)

The introduction of all-oral direct-acting antiviral agents (DAAs) has vastly increased the feasibility of successful HCV treatment. DAAs have superior safety, tolerability and efficacy when compared with older, interferon-based regimens, and HCV clearance can be achieved within 12 weeks of treatment, even in the setting of HIV-related immunosuppression.(3) However, the high cost of DAAs (i.e., approximately \$1000 per pill, with wholesale costs of up to \$100,000 for a full course of treatment(4)) may contribute to disparities in treatment uptake(5) and adherence,(6) limiting the effectiveness of DAAs in real-world clinical practice. Although some studies have reported that sociodemographic and medication access barriers to HCV treatment for HIV/HCV-coinfected individuals are present in the DAA era, they have been limited by small sample sizes, cross-sectional study design, single-site evaluations of uptake, or assessment of only the first year of DAA availability.(6–8)

This study was undertaken to investigate factors associated with DAA initiation and treatment effectiveness during the initial three years of DAA availability in a large cohort of HIV/HCV-coinfected individuals in a U.S.-based integrated healthcare system.

METHODS

Study setting, population and design

We conducted a retrospective cohort study of patients with HIV/HCV coinfection in Kaiser Permanente Northern California (KPNC), which provides comprehensive medical services to over 4 million members. KPNC patients with HIV receive personalized healthcare

planning support from case managers and are prioritized for HCV treatment in accordance with the latest guidelines.(2) HCV care is further coordinated within each medical facility by a lead infectious disease clinician and KPNC-wide by the HCV Task Force, a group of clinicians, researchers and community-based advocates dedicated to improving access to care and delivery of evidence-based treatments for patients with HCV.

Patients included in this study were HIV-infected individuals 18 years old with a positive HCV RNA test or an HCV genotype documented in the KPNC electronic health record at any time during 1997-2017, and at least three months of continuous KPNC membership from October 2014 (when interferon-free DAA regimens became widely available at KPNC with the approval of ledipasvir/sofosbuvir) through December 2017. HIV-infected individuals were identified from KPNC's HIV registry, which includes all known cases of HIV since the early 1980s, confirmed by medical chart review.

Baseline was defined as the latest of October 1, 2014, HCV infection confirmation, HIV infection confirmation, or, KPNC health plan enrollment. To measure rates of DAA initiation, patients were followed until the earliest of a KPNC pharmacy prescription fill for any DAA, health plan disenrollment, death, or end of study follow-up (December 31, 2017). Among patients who initiated DAAs, we obtained laboratory evidence of sustained virologic response (SVR), defined as an HCV RNA level <20 IU/mL at least 11 weeks after completion of treatment. We evaluated SVR at least 11 weeks after the end of treatment, rather than at the 12-week time point used in clinical trials, to allow for variability in timing of laboratory testing in clinical practice. This study was approved by the KPNC institutional review board with a waiver of written informed consent.

Study measurements

Details on study measurements have been described previously.(5) Briefly, the following baseline data were obtained from the KPNC electronic health record: 1) sociodemographic characteristics, including age, sex, race/ethnicity, and census-based neighborhood deprivation index (proxy for socioeconomic status);(9) 2) healthcare-related economic factors, including type of individual health insurance, individual out-of-pocket maximum healthcare costs, and enrollment in the AIDS Drug Assistance Program (ADAP), which covers HIV and HCV prescription medication costs for underinsured individuals living with HIV/AIDS in California;(10) 3) behavioral factors, including HIV-transmission risk factor, alcohol use, smoking, and drug abuse diagnosis; and 4) clinical factors, including HCV genotype, prior HCV treatment, fibrosis level, CD4 count, ART use (defined as a KPNC pharmacy prescription fill for any ART in the year prior to baseline), HIV RNA level, hepatitis B virus infection and number of outpatient visits in the year prior to baseline (proxy for healthcare access). Patients were considered to have advanced liver fibrosis if they had a transient elastography score ≥9.5 kPa in the prior 12 months, (Fibroscan®; Paris, France) or a Fibrosis-4 (FIB-4) score >3.25 in the prior 6 months.(11)

Statistical analyses

The cumulative proportion of patients initiating DAAs was assessed using Kaplan Meier estimates, overall and within key subgroups. Unadjusted and adjusted rate ratios (RRs and

aRRs, respectively) for factors associated with DAA initiation were obtained from Poisson regression models. Each factor possibly associated with DAA initiation was analyzed separately in unadjusted models and those significant at $p < 0.10$ were included in the adjusted model. The proportion with SVR was computed overall and compared by subgroup using Fisher's exact test. Analyses were conducted in Stata 12 (College Station, TX).

RESULTS

A total of 462 HIV/HCV-coinfected patients were included. The cohort was mostly male (88%) and of non-Hispanic White (47%) or Black (28%) race/ethnicity (Table 1). The median age was 55 years. The majority (60%) of patients were enrolled in commercial insurance only; 30% were enrolled in Medicare, a government health insurance program for those age 65 years and older(12); and 8% were enrolled in Medicaid, a government health insurance program for those with limited income or resources.(13) During the study period, 40% were also enrolled in ADAP. HCV genotype 1 was the most prevalent (80%), followed by HCV genotype 2 (9%) and genotype 3 (6%). At baseline, most patients (88%) had no history of HCV treatment and 85% were on ART

From October 2014 through December 2017, 276 out of 462 HIV/HCV-coinfected patients initiated DAAs, corresponding with a cumulative proportion treated of 70.0% (95% CI: 64.9-74.5) at 3 years from baseline. The most common treatment regimen was ledipasvir/sofosbuvir with or without ribavirin (87%), followed by sofosbuvir/velpatasvir (8%) and sofosbuvir with ribavirin (4%). Treatment initiation was highest among commercially insured patients (77.3%, 95% CI: 71.5-82.6) and lowest among patients with CD4 counts < 200 cells/ μ l (30.9%, 95% CI: 17.2-51.3).

In unadjusted Poisson analyses, a lower likelihood of DAA initiation was observed among women (vs. men), Black patients (vs. White), patients with the greatest neighborhood-level deprivation (vs. least deprived), Medicare and Medicaid beneficiaries (vs. commercially insured), patients with a history of smoking or a prior drug abuse diagnosis, patients with no prior HCV treatment, patients with HIV RNA $> 10,000$ copies/mL (vs. < 500), patients with CD4 counts < 200 cells/ μ l (vs. > 500), and patients with hepatitis B infection (Table 1). A higher likelihood of DAA initiation was observed among patients with HCV genotype 1 (vs. all other genotypes). There were no significant differences in DAA initiation by age, individual out-of-pocket maximum healthcare costs, enrollment in ADAP, HIV-transmission risk factor, alcohol use, fibrosis level, use of ART, or number of outpatient visits.

After adjusting for sex, race/ethnicity, neighborhood-level deprivation, insurance type, smoking, drug abuse diagnosis, HCV genotype, prior HCV treatment, CD4 count, HIV RNA level and hepatitis B infection, DAA initiation remained significantly lower in Medicare enrollees (aRR: 0.62, 95% CI: 0.46-0.84), patients with drug abuse diagnoses (aRR: 0.72, 95% CI: 0.54-0.97), patients with CD4 counts < 200 cells/ μ l (aRR: 0.45, 95% CI: 0.23-0.91) and patients with no prior HCV treatment (aRR: 0.68, 95% CI: 0.48-0.97). DAA initiation remained significantly higher in patients with HCV genotype 1 (aRR: 1.42, 95% CI: 1.02-1.98).

Among the 262 patients for whom we were able to assess SVR status, 248 (95%) had undetectable HCV RNA (SVR) and 14 (5%) had detectable HCV RNA (treatment failure). SVR was achieved in 96% of the patients with HCV genotype 1, 81% of patients with genotype 2 and 93% of patients with genotype 3, and response rates were similar across all DAA regimens. Notably, high SVR was achieved in historically difficult-to-treat and high-risk subgroups, including heavy drinkers (8 drinks per week; 100%; 12 treated), people who inject drugs (93%; 70 out of 75 treated), patients with drug abuse diagnoses (95%; 71 out of 75 treated), patients with prior HCV treatment (90%; 37 out of 41 treated), and patients with advanced fibrosis (88%; 23 out of 26 treated). There was no significant difference in likelihood of SVR by any of the patient subgroups examined.

DISCUSSION

In this observational cohort study, more than half (70%) of HIV/HCV-coinfected patients engaged in care were treated during the initial three years of DAA availability within KPNC, with a high proportion achieving SVR (95%). Despite the high cost of DAAs, we did not find significant disparities in DAA initiation by sociodemographic factors such as age, sex, race/ethnicity or socioeconomic status. However, lower DAA initiation was observed among HIV/HCV-coinfected patients enrolled in Medicare, patients with drug abuse diagnoses, patients with lower (i.e. <200) CD4 counts and patients with no prior HCV treatment. Our results highlight the need for efforts to increase DAA uptake in this high-priority population, with particular attention to subgroups of patients that may experience greater barriers to treatment or who are receiving HCV treatment for the first time.

The strongest non-clinical predictor of reduced DAA initiation was enrollment in Medicare. Although all Medicare prescription drug plans cover at least one DAA regimen, treatment may remain cost-prohibitive as total out-of-pocket spending under Medicare can still be as high as \$10,000 for a full course of therapy for enrollees without a low-income subsidy plan. (14) The association of Medicaid enrollment with reduced DAA initiation was expected but did not reach statistical significance in adjusted analyses, possibly because of the small number of Medicaid patients in our cohort (n=36; 8% of total study population). During the study period, California's Medicaid program limited reimbursements for DAAs to patients who had drug and alcohol testing before treatment and who either had a documented period of sobriety or were enrolled in a drug treatment program. (15) Although we did not have patient-specific data on reimbursement denials, these payment limitations may explain the variability in DAA initiation by health insurance type, as well as the lower rate of DAA initiation among patients with a prior drug abuse diagnosis, especially as 61% of Medicaid patients in our study had a prior drug abuse diagnosis.

Lower DAA initiation among patients with a prior drug abuse diagnosis, as also observed in other HIV/HCV-coinfected populations (16, 17) and the overall HCV-infected population within KPNC, (5) could be driven by both provider- and patient-level barriers. While active substance use is not a contraindication for HCV therapy and has not been shown to negatively impact treatment success, providers may opt to defer treatment for some patients due to concerns about reduced adherence to treatment or potential HCV re-infection due to

ongoing high-risk behaviors. (2, 18, 19) Providers and patients may also choose to defer HCV treatment until completion of treatment for substance abuse.

Reduced DAA initiation among those with lower CD4 counts likely reflect clinical decisions. Patients with low CD4 counts may delay HCV treatment to focus on HIV-related health concerns, and some providers may prioritize successful treatment with ART before initiating DAAs.

Similar to prior studies that have evaluated real-world DAA use in HIV/HCV-coinfected patients, (3, 20) we observed a high proportion of treated patients with SVR. Our study adds to evidence demonstrating the high effectiveness of DAAs among HIV/HCV-coinfected patients in routine clinical practice, even among subgroups considered more difficult to treat or those typically underrepresented in clinical trials, including substance users and individuals with prior HCV treatment or advanced fibrosis.(20)

There were some study limitations. First, our cohort was primarily male, reflecting the epidemiology of HIV/HCV coinfection in our setting, and potentially limiting the generalizability of our results to females. Second, our results may not be generalizable to non-integrated health systems, settings without individual case management of HIV patients or specialty HCV care, or uninsured populations. Barriers to DAA initiation may also differ in countries with different health financing mechanisms or where a limited number of DAA regimens are approved for use. However, the KPNC membership is representative of the surrounding population and HIV patients at KPNC are demographically similar to AIDS cases statewide.(21) Third, we were unable to directly measure patients' out-of-pocket costs. However, we included other proxies for cost, such as healthcare coverage variables and census-based socioeconomic status, which were lacking in prior studies. Fourth, patients who filled their DAA medications at a non-KPNC pharmacy would not have been captured, although this is expected to be minimal as surveys show most patients purchase their medications at KP pharmacies.(22) Lastly, while the focus of this study was on patient-level factors related to DAA initiation, other factors, including provider- or health systems-level factors and factors not systematically captured in electronic health records (e.g. declination of DAAs by patient, deferral of DAAs to avoid HIV-HCV drug-drug interactions), may also play a role in DAA initiation.

Our study also had several strengths, including assessment of DAA initiation in a large cohort using real-world data from clinical practice; high-quality and comprehensive ascertainment of HIV and HCV infection; and, broad evaluation of patient-level predictors of DAA initiation including sociodemographic, economic, clinical and behavioral factors.

CONCLUSIONS

In this cohort study of DAA uptake and outcomes among HIV/HCV-coinfected patients in clinical practice, we found few sociodemographic disparities in DAA initiation and high treatment effectiveness. To maximize the benefits of highly effective DAAs, enhanced efforts are needed to further prioritize HIV/HCV-coinfected populations for treatment, especially patient subgroups that may experience greater obstacles to treatment initiation,

including Medicare enrollees, patients with a history of drug abuse disorders, patients with low CD4 count, and patients who are receiving HCV treatment for the first time.

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Table 1.

Characteristics of HIV/HCV-coinfected patients at baseline and likelihood of DAA initiation in Kaiser Permanente Northern California, October 2014 to December 2017

	n	(%)	Unadjusted RR (95% CI)	Adjusted RR (95% CI) ^I
TOTAL	N=462	(100)	-	-
Sociodemographic				
Age at baseline, median (IQR)	55 (26-75)		-	-
<50	128	(27.7)	Ref	
50-59	193	(41.8)	1.04 (0.77-1.40)	
60-69	130	(28.1)	1.09 (0.79-1.51)	
70	11	(2.4)	0.58 (0.23-1.44)	
Female	57	(12.8)	0.52 (0.34-0.81)	0.70 (0.44-1.10)
Race/ethnicity				
White, non-Hispanic	216	(46.8)	Ref	Ref
Black, non-Hispanic	128	(27.7)	0.71 (0.54-0.95)	0.85 (0.62-1.17)
Hispanic	75	(16.2)	0.95 (0.68-1.33)	0.92 (0.65-1.30)
Asian, non-Hispanic	15	(3.2)	1.09 (0.57-2.00)	0.91 (0.48-1.75)
Other	25	(5.4)	0.54 (0.30-0.98)	0.59 (0.32-1.09)
Unknown	3	(0.6)		
Neighborhood deprivation index				
1 (least deprived)	138	(29.9)	Ref	Ref
2	94	(20.3)	0.86 (0.62-1.21)	0.79 (0.56-1.12)
3	113	(24.5)	0.89 (0.66-1.21)	0.93 (0.67-1.29)
4 (most deprived)	117	(25.3)	0.59 (0.42-0.82)	0.74 (0.51-1.07)
Economic				
Insurance type				
Commercial only	275	(59.5)	Ref	Ref
Medicare	137	(29.7)	0.58 (0.44-0.76)	0.62 (0.46-0.84)
Medicaid	36	(7.8)	0.43 (0.25-0.74)	0.66 (0.38-1.16)
Unknown	14	(3.0)		
Annual out-of-pocket maximum				
\$3000	270	(58.4)	Ref	
>\$3000	178	(38.5)	0.96 (0.77-1.21)	
Unknown	14	(3.0)		
ADAP enrollment	186	(40.3)	1.17 (0.92-1.48)	
Behavioral				
HIV-transmission risk				
Heterosexual	50	(10.8)	Ref	
Injection drug use	150	(32.5)	0.89 (0.59-1.34)	
Men who have sex with men	219	(47.4)	1.11 (0.76-1.63)	

	n	(%)	Unadjusted RR (95% CI)	Adjusted RR (95% CI) ¹
TOTAL	N=462	(100)	-	-
Other/Unknown	43	(9.3)	0.70 (0.40-1.21)	
Alcoholic drinks per week				
0	265	(57.4)	Ref	
1-7	66	(14.3)	1.17 (0.83-1.65)	
8	20	(4.3)	1.47 (0.81-2.64)	
Unknown	111	(24.0)		
Ever smoked	228	(49.4)	0.73 (0.58-0.92)	0.96 (0.74-1.24)
Drug abuse diagnosis	166	(35.9)	0.56 (0.43-0.72)	0.72 (0.54-0.97)
Clinical				
HCV genotype 1	369	(79.9)	1.41 (1.03-1.94)	1.42 (1.02-1.98)
Non-DAA HCV treatment-naïve	408	(88.3)	0.60 (0.44-0.84)	0.68 (0.48-0.97)
Advanced fibrosis				
No	209	(45.2)	Ref	
Yes	49	(10.6)	0.85 (0.57-1.28)	
Unknown	204	(44.2)		
CD4 count (cells/μl)				
500	277	(60.0)	Ref	Ref
200-499	136	(29.4)	0.80 (0.62-1.04)	1.03 (0.78-1.37)
<200	32	(6.9)	0.29 (0.15-0.56)	0.45 (0.23-0.91)
Unknown	17	(3.7)		
HIV RNA level (copies/mL)				
<500	389	(84.2)	Ref	Ref
500-9,999	21	(4.5)	0.55 (0.28-1.07)	0.61 (0.31-1.22)
10,000	41	(8.9)	0.58 (0.35-0.94)	0.72 (0.43-1.22)
Unknown	11	(2.4)		
Use of antiretroviral therapy ²	391	(84.6)	1.34 (0.93-1.92)	
Hepatitis B infection	45	(9.7)	0.54 (0.33-0.87)	0.65 (0.40-1.06)
Number of outpatient visits in year prior to baseline				
0	19	(4.1)	Ref	
1	111	(24.0)	2.11 (0.97-4.57)	
2	84	(18.2)	1.71 (0.78-3.77)	
3	248	(53.7)	1.50 (0.70-3.21)	

¹ Adjusted for all variables significant in unadjusted models.

² Defined as any prescription fill for antiretroviral therapy in the year prior to baseline

Abbreviations: ADAP= AIDS Drug Assistance Program; HCV=hepatitis C virus; HIV=human immunodeficiency virus; IQR=interquartile range; RR=rate ratio

Estimates significant at p<0.05 listed in bold.