Treating Hepatitis C in a Ryan White-Funded HIV Clinic: Has the Treatment Uptake Improved in the Interferon-Free Directly Active Antiviral Era?

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Abstract

Now that highly efficacious, interferon-free (IFN-free), direct acting antivirals (DAA) for the treatment of hepatitis C (HCV) have closed the gap between treatment and cure, identifying barriers that prevent initiation of treatment is more crucial than ever. This is a retrospective study utilizing Electronic Medical Records and Prior Authorization Records to identify HCV treatment gaps, including predictors for intention-to-treat and treatment initiation in the first 15 months of a Ryan White funded human immunodeficiency virus (HIV)/HCV co-infection clinic. This study included 128 adults ≥ 18 years old with HIV and chronic HCV infection who had visited the treatment center at least once since January 2013. Provider intent-to-treat was used to differentiate patients actively considered for treatment based on documentation kept by a multidisciplinary HCV team. Members of this group who had gone on to initiate treatment were identified. Baseline characteristics were compared. Rates of active treatment consideration and treatment initiation were 30% and 14%, respectively. HCV treatment-naïve individuals were less likely to be considered for treatment [risk ratio (RR) 1.58, 95% confidence interval (CI) 1.07–2.32] and initiate therapy (RR 2.33, 95% CI 0.97–5.60). Advanced liver disease had no significant association. Black race (RR 1.96, 95% CI 0.90–4.25) and Medicaid insurance holders (RR 1.90, 95% CI 0.95–3.82) tended to be less likely to initiate therapy. The availability of IFN-free DAA regimens has yet to increase HCV treatment uptake in our HIV/HCV co-infected population. Barriers to HCV treatment initiation have shifted from medical contraindications to socioeconomic variables.

Introduction

ADVANCED LIVER DISEASE HAS EMERGED as a leading cause of morbidity and non-AIDS related deaths among HIV-infected individuals.¹ Hepatitis C virus (HCV) and HIV have shared routes of transmission, and high rates of new HCV infections have been demonstrated in HIV-infected men who have sex with men (MSM).² Although annual screening for the HCV antibody is recommended for this at-risk population, at least 50% of all HCV-infected individuals remain undiagnosed.³ Of those with known HIV/HCV co-infection, very few individuals historically have received treatment for HCV.^{4,5}

The Health Resources and Services Administration's HIV/AIDS Bureau (HRSA/HAB) has identified increasing HCV treatment among HIV-infected patients as a priority. Ryan

White funded clinics are not only expected to offer HCV treatment but also to take steps to address barriers that limit access to HCV treatment.⁶ The availability of highly efficacious, interferon-free (IFN-free), all oral, direct acting antivirals (DAAs) has transformed the landscape of treatment for HCV infection and substantially increased the feasibility of offering treatment to the majority of co-infected patients.⁴

However, the overall experience of individual Ryan White Programs in the current IFN-free DAA era, including intent-to-treat rates, treatment uptake rates, and factors associated with initiating HCV therapy, are unknown. In this context, we aimed to identify persistent gaps in HCV treatment by determining predictors for intention-to-treat and HCV treatment uptake 15 months after the initiation of an HIV/HCV Co-Infection Clinic within an urban, Ryan White-funded, Level 3 Patient Centered Medical Home

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(PCMH). We also report our experience in terms of regimens chosen, completion rate, and safety.

Methods

A retrospective chart review was done at the University of Pittsburgh Medical Center (UPMC). This study received exempt approval from the University of Pittsburgh's Institutional Review Board (IRB). All patients ≥ 18 years old with HIV and chronic HCV (defined as a detectable HCV RNA PCR on or after January 1, 2014) seen at the center at least once between January 2013 and August 2014 were included in the study. Demographic information, visit history, treatment history, and laboratory values were collected for all included patients. Liver staging was done with the APRI (AST to Platelet Ratio Index) and FIB-4 (Fibrosis 4) score. A FIB-4 score ≥ 2 was considered consistent with advanced liver fibrosis based on research presented by the CDC at the 2015 Conference for Retroviruses and Opportunistic Infections.^{7,8}

A multidisciplinary team maintained a list of patients whose HIV provider had explicit intent to initiate HCV treatment (active consideration group) between January 1, 2014 and March 31, 2015. Patients were placed on this list if the provider felt the patient was ready to begin the process of obtaining prior authorization for treatment. This was based on the clinical judgment of the individual provider. Steps to obtaining prior authorization may have included a medication change to avoid a drug-drug interaction or obtaining updated laboratory and imaging results to include in the application. Patients were excluded from active treatment consideration based on the discretion of the provider. Possible reasons for exclusion may have included uncontrolled HIV viremia, prioritization of more urgent health concerns, or unstable housing situations. Names of patients who had initiated HCV treatment were derived from the list of actively considered patients.

Baseline characteristics were compared between groups (actively considered vs. not actively considered; initiated treatment vs. failed to initiate treatment). Assessment of social factors that may influence HIV or HCV treatment, such as drug and alcohol use, are routinely documented at each office visit for all patients. Reasons for not initiating treatment were obtained from the Electronic Medical Record (EMR) and records of prior authorizations. Patients who had started HCV treatment were reviewed for adverse effects and laboratory abnormalities, which were graded on a scale of 1–4 based on Package Insert criteria and the DHHS Common Terminology Criteria for Adverse Events.⁹

The choice of treatment regimen depended primarily on available FDA-approved agents at the time of treatment consideration and limiting drug-drug interactions between antiretroviral therapy and available DAAs. Sofosbuvir (SOF) and simeprevir (SMV) +/- ribavirin (RBV) was the regimen initially submitted to insurance companies for approval until ledipasvir/sofosbuvir (LDV/SOF) became the preferred treatment regimen following its approval in October 2014. If two or more attempts for treatment with SOF/SMV were denied, treatment with SOF + RBV +/- pegylated interferon (PEG-IFN) was utilized. Patients requiring use of PEG-IFN were excluded from the final analysis as our intent was to describe rates of IFN-free treatment uptake only.

Statistical analysis was performed utilizing Microsoft Excel. Risk Ratios (RR) and 95% Confidence Intervals

(95% CI) were calculated to determine factors associated with evaluation and treatment for HCV. If the confidence interval did not include 1, the result was considered statistically significant.

Results

Overall, 128 HIV/HCV co-infected patients met inclusion criteria. Sixty-eight percent of patients were male, 61% were older than 55 years, 57% were black, 73% had genotype 1, 1a, or 1b infection, 75% were HCV treatment naïve, and 48% had a FIB-4 score ≥ 2 , indicating advanced fibrosis. Baseline patient characteristics are shown in Table 1. The list of patients actively considered for treatment contained 42 names, and 22 of these had started treatment as of March 31, 2015. Four patients were treated with IFN-containing regimens and excluded, bringing the final number of patients considered and started to 38 and 18, respectively.

Statistically significant predictors of not being actively considered for HCV treatment included: (1) age < 55 (OR 1.97, 95% CI 1.56–5.74); (2) detectable HIV viremia (RR 1.27, 95% CI 1.01–1.61); (3) not having a known genotype (RR 1.63, 95% CI 1.40–1.89); (4) being HCV treatment naïve (RR 1.58, 95% CI 1.07–2.32); (5) no prior liver imaging (RR 1.48, 95% CI 1.21–1.81); and, (6) no prior liver biopsy (RR 1.69, 95% CI 1.24–2.33). Race, type of insurance, appointment history, baseline HCV RNA level, and advanced liver disease were not predictive of intent to treat.

Of the 38 patients actively considered for treatment, only 18 initiated therapy. Among these 18 patients, 83% met criteria for high or the highest priority for treatment as per AASLD/IDSA/IAS-USA HCV Treatment Guidelines.¹⁰ Significant predictors associated with failure to initiate HCV therapy despite active consideration included being female (RR 2.02, 95% CI 1.03–3.95) and being HCV treatment naïve (RR 2.33, 95% CI 0.97–5.60). Factors that trended towards statistical significance for failing to start HCV treatment were: black race (RR 1.96, 95% CI 0.90–4.25) and Medicaid insurance (RR 1.90, 95% CI 0.95–3.82).

Table 2 describes the barriers to being actively considered for treatment. In our cohort, failure to keep regular medical appointments ($\sim 30\%$), active alcohol or illicit substance use ($\sim 23\%$), and another medical condition requiring prioritized attention ($\sim 18\%$) were the leading reasons why patients were not actively considered for HCV treatment.

Due to drug-drug interactions, antiretroviral therapy (ART) was switched in preparation for HCV treatment in 14/38 (37%) patients. Of the 14 patients who underwent ART switch, 9 were on NNRTI-based regimens, 3 were on PI-based regimens, and 2 were on cobicistat-containing regimens. The majority of patients were changed to rilpivirine (60%), with raltegravir and dolutegravir being other common choices. Insurance companies frequently required at least one appeal to be submitted prior to approving therapy, making the mean time between initial evaluation for HCV therapy and prior authorization approval 67.5 days (SD 83.7). The most frequent reasons for insurance denial were need for additional or updated information, different HCV therapy preferred on formulary, and not meeting criteria for immediate treatment.

Sixty-seven percent of patients were treated with SOF/LDV; 17% with SOF/SMV $\pm$ RBV; and 17% with SOF + RBV. At the time of submission, 10 patients have completed

TABLE 1. BASELINE CHARACTERISTICS AND PREDICTORS FOR PATIENTS NOT ACTIVELY CONSIDERED AND FAILING TO INITIATE HCV TREATMENT WITH DIRECTLY ACTIVE ANTIVIRALS (N=128)

Characteristic	Actively considered for HCV treatment (N=42)	Not actively considered for HCV treatment (N=86)	Risk ratio (95% CI)	Initiated on HCV treatment (N=18)	Failed to initiate HCV treatment (N=20)	Risk ratio (95% CI)
Age <55	2 (5%)	48 (56%)	1.97^a (1.56–5.74)	5 (28%)	11 (55%)	1.69 (0.92–3.06)
Age >55	40 (95%)	38 (44%)	Ref	13 (72%)	9 (45%)	Ref
Black race	26 (62%)	49 (57%)	0.94 (0.73–1.19)	8 (44%)	15 (75%)	1.96 (0.90–4.25)
Non-black race	16 (38%)	37 (43%)	Ref	10 (56%)	5 (25%)	Ref
Female	12 (29%)	27 (31%)	1.04 (0.80–1.34)	5 (28%)	12 (60%)	2.02^a (1.03–3.95)
Male	29 (69%)	58 (68%)	Ref	13 (72%)	7 (35%)	Ref
Transgender	1 (2%)	1 (1%)	N/A	0 (0%)	1 (5%)	N/A
Appt history <80%	22 (52%)	48 (56%)	1.05 (0.82–1.33)	8 (44%)	12 (60%)	1.35 (0.72–2.53)
Appt history >80%	20 (48%)	38 (44%)	Ref	10 (56%)	8 (40%)	Ref
HIV VL >40	6 (15%)	24 (29%)	1.27^a (1.01–1.61)	4 (22%)	4 (20%)	0.94 (0.43–2.02)
HIV VL <40	36 (85%)	61 (71%)	Ref	14 (78%)	16 (80%)	Ref
HCV RNA level >6 million IU/mL	5 (12%)	17 (20%)	1.20 (0.92–1.57)	4 (22%)	1 (5%)	0.35 (0.06–2.05)
HCV RNA level <6 million IU/mL	37 (88%)	67 (78%)	Ref	14 (78%)	19 (95%)	Ref
HCV RNA level unknown	0 (0%)	2 (2%)	N/A	0 (0%)	0 (0%)	N/A
<i>HCV genotype</i>						
Unknown	0 (0%)	19 (22%)	1.63^a (1.40–1.89)	0 (0%)	0 (0%)	N/A
Known	42 (100%)	67 (78%)	Ref	18 (100%)	20 (100%)	N/A
1, 1A, 1B	38 (91%)	56 (65%)	N/A	15 (83%)	19 (95%)	N/A
2	1 (2%)	1 (1%)	N/A	1 (6%)	0 (0%)	N/A
3	2 (5%)	6 (7%)	N/A	2 (11%)	0 (0%)	N/A
4	0 (0%)	4 (5%)	N/A	0 (0%)	0 (0%)	N/A
Dual	1 (2%)	0 (0%)	N/A	0 (0%)	1 (5%)	N/A
<i>APRI</i>						
<1.0	35 (83%)	65 (76%)	0.86 (0.67–1.10)	15 (83%)	16 (80%)	0.9 (0.44–1.87)
>1.0	7 (17%)	22 (26%)	Ref	3 (17%)	4 (20%)	Ref
<0.7	25 (60%)	53 (62%)	N/A	9 (50%)	14 (70%)	N/A
0.7–1.0	10 (24%)	12 (14%)	N/A	6 (33%)	2 (10%)	N/A
1.1–1.5	3 (7%)	9 (11%)	N/A	2 (11%)	1 (5%)	N/A
>1.5	4 (10%)	13 (15%)	N/A	1 (6%)	3 (15%)	N/A
<i>FIB4</i>						
<2.0	20 (48%)	46 (54%)	1.08 (0.85–1.38)	6 (33%)	12 (60%)	1.67 (0.89–3.12)
≥2.0	22 (52%)	40 (46%)	Ref	12 (67%)	8 (40%)	Ref
2.0–3.7	16 (38%)	24 (28%)	N/A	9 (50%)	6 (30%)	N/A
≥3.8	6 (14%)	16 (19%)	N/A	3 (17%)	2 (10%)	N/A
<i>Treatment history</i>						
No prior HCV treatment	25 (60%)	71 (83%)	1.58^a (1.07–2.32)	8 (44%)	16 (80%)	2.33 (0.97–5.60)
Prior HCV treatment	17 (40%)	15 (17%)	Ref	10 (56%)	4 (20%)	Ref
No liver imaging	3 (7%)	26 (30%)	1.48^a (1.21–1.81)	1 (6%)	2 (10%)	1.30 (0.55–3.07)
Liver imaging	39 (93%)	60 (70%)	Ref	17 (94%)	18 (90%)	Ref
No liver biopsy	16 (38%)	63 (73%)	1.69^a (1.24–2.33)	13 (72%)	13 (65%)	0.86 (0.46–1.58)
Liver biopsy	26 (62%)	23 (27%)	Ref	5 (28%)	7 (35%)	Ref
<i>Insurance</i>						
Medicaid	16 (38%)	33 (39%)	1.08 (0.82–1.42)	5 (28%)	10 (50%)	1.90 (0.95–3.82)
Private insurance or Medicare	23 (55%)	38 (44%)	Ref	13 (72%)	7 (35%)	Ref
Medicare	17 (40%)	28 (33%)	N/A	9 (50%)	7 (35%)	N/A
Private	6 (14%)	10 (12%)	N/A	4 (22%)	0 (0%)	N/A
Uninsured	3 (7%)	8 (9%)	N/A	0 (0%)	3 (15%)	N/A

N/A, Statistical tests not performed/applicable; Ref, Reference; ^a*p* < 0.05.

therapy and all individuals eligible for SVR12 monitoring had achieved cure. The most common adverse effects reported by patients who received SOF/LDV were fatigue (3/11), insomnia (1/11), and myalgia (1/11). One individual receiving SOF/SMV experienced a photosensitivity reaction (Grade 1). No hospitalizations occurred during treatment.

Discussion

Treatment gap persists

This is one of the first studies to report on uptake rates for HCV treatment among HIV co-infected patients in the IFN-

free DAA era. During the first 15 months of our HIV/HCV Co-Infection Clinic, less than 30% of our co-infected patients were actively considered for treatment and a mere 14% initiated therapy. These surprising and disappointing findings highlight how treatment consideration and initiation rates remain remarkably similar to historical rates from the IFN-based therapy era.¹¹ As a result, despite high expectations for HCV cure in those who undergo treatment, it is clear that a large gap persists between efficacy and effectiveness.

Our data demonstrate a notable shift in terms of barriers to treatment consideration and uptake. Similar to previous studies, ongoing alcohol abuse, substance abuse, psychiatric

TABLE 2. DESCRIPTION OF BARRIERS
FOR PATIENTS NOT ACTIVELY CONSIDERED
FOR HCV TREATMENT (N=86)

Description	Total	%
Lost to follow-up ^a (>6 months since last visit)	14	16%
Follow-up needed (no known barrier)	12	14%
Deceased	5	6%
Patient declined	7	8%
HCV treatment not priority: more urgent health concern	9	11%
HCV treatment not priority: HIV control not achieved	6	7%
HCV treatment not priority: minimal liver disease	2	2%
Active alcohol abuse	10	12%
Active illicit substance use	9	11%
Uncontrolled psychiatric illness	4	5%
Predicted poor adherence	2	2%
Unstable housing	2	2%
Insurance issues	2	2%
Incarceration	1	1%
Unsure of mental capacity for decision making	1	1%
Decompensated liver disease (ineligible for treatment)	0	0%

^aIncludes patients who relocated, transferred care and/or lost to follow up.

illness, and chaotic social circumstances continued to present substantial obstacles to HCV therapy.^{12,13} However, very few medical contraindications were noted by providers. This is in stark contrast to previous reports where the majority (>80%) of patients had absolute or relative medical contraindications to interferon therapy, such as end-stage liver disease or advanced HIV disease.¹⁴

Active substance use, including injection drug use, is no longer considered a contraindication to HCV therapy in the right treatment setting.¹⁰ Studies show comparable treatment adherence and efficacy rates among substance users compared with persons who do not inject drugs.¹⁵ Additionally, reinfection rates are noted to be low following treatment.¹⁶ Further risk reduction strategies may need to be integrated into the clinical setting to reduce the number of patients for which active alcohol or illicit drug use is considered a barrier to active treatment consideration.

Who is most likely to initiate HCV therapy?

Although DAAs are expected to increase access to therapy for populations previously contraindicated to older regimens, those who had previously been treated for HCV were significantly more likely to have been actively considered for treatment by our clinic. Patients who were white, male, HCV treatment experienced, and privately insured or covered by Medicare were most likely to initiate HCV therapy.

While race was not associated with being considered for HCV treatment, black patients were less likely to initiate therapy despite consideration. Racial disparities have previously been documented in the IFN era.¹⁷ Reasons for persistence of these differences are incompletely understood, however, likely reflect a higher burden of social, psychiatric, and substance abuse related barriers among blacks.¹⁸

Surprisingly, having significant liver fibrosis was not associated with either prioritized consideration for or initiation of HCV treatment. Advanced liver disease is the leading cause of death among HIV/HCV co-infected populations, and these patients are likely to derive the greatest survival benefit from treatment.¹⁹ Attempts should be made to prioritize HCV treatment among such individuals, and strategies to mitigate barriers among those with advanced liver disease are urgently needed. Education and clinic level dialogue among providers on patient criteria that call for immediate treatment may also be helpful.

Drug–drug interactions and obtaining prior authorizations constitute a significant barrier

In addition to the barriers outlined above, managing drug–drug interactions between DAAs and ART,²⁰ submitting prior authorizations, pursuing the appeal process following insurance denials, obtaining health insurance, and communicating with patients constitute significant barriers to initiating HCV treatment. Despite a multidisciplinary team investing significant provider, pharmacist, and social worker time and effort, on average 67.5 days were needed to obtain approval. While multiple HCV treatment regimens are now available, each insurance payer may have a preferred therapy on formulary. Prescribing a treatment other than what is preferred may require patient-specific justification, such as the presence of a drug–drug interaction.

A recent systematic evaluation of Medicaid policies for reimbursement of sofosbuvir reported that 74% of states limited access to those with advanced fibrosis.²¹ Two-thirds had restrictions based on prescriber type, and 88% included drug or alcohol use in the eligibility criteria. Many states are currently lobbying to eliminate or soften such restrictions in an effort to improve treatment access.

Limitations

This is a single-center, retrospective study, which is likely underpowered to detect statistical significance between groups. Multivariate analysis was not pursued on account of the small sample size.

The process of patient selection for HCV treatment was not standardized. While this mirrors real life practice, the clinical judgment of individual providers is subject to significant variation. The presence of potential barriers to treatment was described only for those who were not considered for treatment, constituting a significant barrier when looking to make a comparison between groups. As many of the defined barriers are subjective, it is difficult to infer if barriers such as “more urgent health concern” were also present in the actively considered group, since this would not be routinely documented. As this study looks only at a snapshot in time one year after the clinic’s initiation, it is unknown if the patients in the active consideration group overcame barriers to treatment consideration during the study time period. Data pertaining to the reasons those with advanced liver disease were not considered for treatment was not specifically abstracted and cannot be reported.

Conclusions

DAAs may have closed the gap between treatment and cure, but barriers to initiating HCV treatment persist among

HIV/HCV co-infected individuals. Additionally, treatment teams and patients face multiple hurdles in accessing HCV treatment. Multidisciplinary strategies can successfully overcome these hurdles. However, the dedicated time and effort required for a patient to successfully initiate and complete a course of HCV treatment must be acknowledged, and sufficient staffing resources that are fiscally supported must be made available. This is a mission far from accomplished.

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Author Disclosure Statement

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