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Attitudes and Potential Barriers towards Hepatitis C Treatment in Patients with and without HIV Coinfection

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Abstract

This study aimed to assess attitudes and potential barriers towards treatment in patients with hepatitis C virus (HCV) infection, comparing those with and without HIV coinfection. A cross-sectional survey of 82 HCV-infected adults with and without HIV was conducted in greater Los Angeles between November 2013 and July 2015. Overall, there were 53 (64.6%) with HIV coinfection, 20 (25.0%) with self-reported cirrhosis, and 22 (26.8%) with a history of prior HCV treatment. 93.2% wanted HCV treatment, but 45.9% were unwilling/unable to spend anything out of pocket, 29.4% were waiting for new therapies, and 23.5% were recommended to defer HCV treatment. HIV/HCV-coinfected patients were more likely to want treatment within 1 year (90.2% versus 68.2%, $p = 0.02$), more willing to join a clinical trial (74.5% versus 8.0%, $p < 0.01$), more willing to take medications twice daily (86.3% versus 61.5%, $p = 0.01$), and more likely to prefer hepatitis C treatment by an infectious diseases/HIV physician (36.7% versus 4.0%, $p < 0.01$). 77.1% of coinfected patients were willing to change antiretroviral therapy if necessary to treat HCV, but only 48.0% of patients were willing to take a medication if it had not been studied in HIV-positive patients. Treatment preferences differ between HIV/HCV-coinfected and HCV-monoinfected patients. Despite a strong willingness among the study cohort to start HCV treatment, other factors such as cost, access to medications, and provider reluctance may be delaying treatment initiation.

Keywords

Human Immunodeficiency Virus (HIV); Hepatitis C Virus (HCV); Barriers; Survey

Introduction

An estimated 170 million people worldwide are infected with chronic hepatitis C (HCV) with United States estimates ranging from 2.7–3.5 million actively infected persons (1–3).

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Only about half of those living with hepatitis C in the United States are aware of their diagnosis and only approximately 16% have ever been prescribed HCV treatment (4).

Up to 25% of the roughly 1.2 million people infected with HIV-1 in the United States are coinfected with HCV (5). HIV hastens hepatitis C disease, resulting in higher rates of fibrosis, liver failure, and death among HIV/HCV-coinfected patients compared to HCV-monoinfected patients (6–7). Despite the high risk of progression to cirrhosis among HIV/HCV-coinfected individuals, historical treatment rates have been even lower in this population on the order of 1–7% (8), with limited treatment uptake in the pegylated interferon/ribavirin era associated with comorbid medical and psychiatric conditions, poorly-controlled HIV, and ongoing substance abuse (9).

The introduction of direct acting antivirals (DAAs) has radically changed the treatment landscape for HCV and increased the feasibility of providing treatment to coinfected patients, but early reports suggest that uptake remains low in some clinics (10). Insurance access (11), ongoing substance abuse, immunosuppression (CD4 < 200 cells/mm^3), hepatic decompensation, and patient refusal have been identified as potential barriers to HCV treatment in those with HIV (12). The presence of these barriers in addition to lack of engagement in care, unstable housing, uncontrolled psychiatric disease, and uncontrolled HIV have been associated with lower likelihood of referral for HCV treatment (13). This analysis aims to quantify barriers to HCV treatment in our population and to qualify attitudes towards HCV treatment among HIV/HCV-coinfected individuals in comparison to HCV-monoinfected patients that may suggest other potential barriers.

Methods

We conducted a cross-sectional survey study of HCV-infected individuals with and without HIV coinfection between November 2013 and July 2015. Adults 18 years of age or older with active hepatitis C infection were eligible to participate; those with a prior history of treated and cured HCV infection were excluded. Active infection was determined by the referring provider. Participants were recruited in the greater Los Angeles area from the UCLA HIV Research Study Volunteer Project (RSVP) database, community outreach events, 3 community clinics and 2 university clinics (HIV and Hepatology). Surveys were conducted on paper, online, or over the phone. Randomly generated identification numbers were provided to online participants to avoid duplicate and unsolicited submissions.

The questionnaire included self-reported demographics information (age, gender, marital status, education level, employment, annual income, housing, ethnicity), overall health, HIV status, HIV complications, and HIV treatment, presence of cirrhosis, HCV treatment history and reasons for not having received treatment if applicable. Participants answered a series of questions regarding HCV treatment preferences with responses corresponding to a 5-point Likert scale.

Data analysis was performed using JMP Pro 12.0.1 (SAS Institute Inc., Cary, NC). Descriptive statistics were performed for the overall cohort and for each subgroup (HCV-monoinfected and HIV/HCV-coinfected). Total number of responses and percentages

(missing values excluded) were calculated for categorical variables; median and interquartile ranges were calculated for continuous variables. Statistical significance between groups was calculated using Chi-square and t-tests for categorical and continuous variables respectively with a p-value threshold of < 0.05.

This study was conducted with the approval of the UCLA Institutional Review Board.

Results

A total of 82 participants completed the survey between November 2013 and July 2015, including 53 (65%) with HIV coinfection, and 20 (25%) with self-reported cirrhosis. As shown in Table 1, the median age was 56 years (IQR 49–60). The majority (74%) of participants were male with a higher proportion of males in those with HIV coinfection (87% versus 52%, $p < 0.01$). Forty-three (57%) identified as being of non-White race or ethnicity, including 18 (24%) Black or African American, and 17 (22%) Hispanic. The majority had attended at least some college (48, 59%), 29 (35%) were employed, and only 3 (4%) reported active non-tetrahydrocannabinol (THC) drug use. Nearly all (77, 97%) reported some form of insurance or third-party payer. Thirty-one (39%) had received prior HCV treatment, 52% with interferon. Nine participants (6 monoinfected and 3 coinfected) were receiving HCV treatment at the time of the survey.

Of those with HIV, 94% were on antiretroviral therapy (ART) with varying regimens: integrase inhibitor in 26 (50%), protease inhibitor in 19 (37%), and a non-nucleoside reverse transcriptase inhibitor (NNRTI) in 8 (15%); 1 person did not report their regimen. Forty-six (94%) reported CD4 > 200 cells/mm^3. Those with HIV were less likely to be married or in a long-term relationship (21% versus 41%, $p = 0.047$) and more likely to have an income of less than $25,000 per year (78% versus 29%, $p < 0.01$). There was a trend towards less stable housing in those with HIV (77% versus 93%, $p = .074$). HIV/HCV-coinfected participants also trended towards being less likely to have had prior HCV treatment (31% versus 52%, $p = 0.063$).

In the overall cohort, 68 (93.2%) desired HCV treatment at some point (92.3% excluding the 9 already on treatment). Only 12 (17.6%) were willing to wait 2 or more years to treat their HCV infection. 34 (45.9%) were unwilling to spend any money out of pocket, while 30% were willing to spend over $500. Fifty-five (72.4%) preferred treatment by a physician over a nurse practitioner. These values were not statistically different between the monoinfected and coinfected groups.

Participants not on treatment reported a variety of reasons for not receiving HCV treatment including 20 (29.4%) waiting for new medications to become available, 16 (23.5%) being told by their physician that they do not need treatment right now, including 11 (22.4%) of HIV/HCV-coinfected individuals versus 5 (26.3%) in HCV-monoinfected, 9 (13.2%) being worried about potential side effects, and 4 (5.9%) never having discussed treatment with their provider. None of these responses were statistically significant between subgroups.

The majority of HIV/HCV-coinfected participants were willing to change their HIV medications if necessary to treat their HCV infection (37, 77.1%). Less than half of those

with HIV/HCV-coinfection were willing to take HCV medications not yet studied in HIV-infected individuals (24, 48.0%). Compared to HCV-monoinfected participants, HIV/HCV-coinfected individuals were more likely to prefer HCV treatment by an ID/HIV specialist (36.7% versus 4.0%, $p < 0.01$), to want HCV treatment within 1 year (90.2% versus 68.2%, $p = 0.02$), to consider joining a clinical treatment trial (74.5% versus 8.0%, $p<0.01$), and to be willing to take medications twice a day if needed (86.3% versus 61.5%, $p = 0.01$). Table 2 summarizes these findings.

Discussion

In this cross-sectional study of HCV-infected individuals with and without HIV coinfection, we specifically asked those participants not on treatment why they had not yet started. We also asked a series of questions assessing attitudes towards treatment that explored other potential barriers and compared these attitudes between HCV-monoinfected and HIV/HCV-coinfected participants. As detailed below, we did not find many of the previously identified barriers to treatment in this cohort such as active substance abuse, advanced immunosuppression, or patient refusal, but did identify several other potential barriers including those at the patient level (for example, lack of awareness of new medications with minimal side effects) and those at the provider level (for example, providers not discussing treatment at all or patients being told they could wait for treatment). We also found that HIV/HCV-coinfected participants were more likely to prefer treatment by an ID/HIV specialist, more likely to want treatment within a year, more likely to take medications twice a day, and more willing to join a clinical trial. We had hypothesized that patients with HIV would be unwilling to change their HIV medications to treat HCV, but this was not the case.

We initially suspected that lack of patient willingness to start treatment limited treatment uptake, but found overwhelmingly the opposite, with 93.2% wanting treatment. Those with HIV desired treatment sooner than those with HCV monoinfection. Those with HIV were also more willing to join clinical trials, which may in part reflect difficulty in accessing HCV medications among the HIV-positive patients outside of clinical trials during the study timeframe and possibly reflects a greater familiarity of HIV patients with clinical trials in this cohort.

With respect to previously identified barriers of active substance use, advanced immunosuppression, decompensated liver failure, patient refusal, and low socioeconomic status(9,12–13), we found relatively low rates of substance abuse with only 4% reporting active substance use other than cannabis, low rates of advanced immunosuppression with only 6.1% of HIV patients reporting CD4 counts ≤ 200 cells/mm^3, anticipated low likelihood of decompensated liver failure with only 25% of patients reporting cirrhosis, and low rates of patient refusal with 93.2% wanting treatment. These low numbers argue against these as potential factors in our HIV/HCV-coinfected population. We did not look at rates of psychiatric illness or history of non-adherence, which have previously been associated with non-treatment (14). We did find, however, that a large proportion of our participants had low income (61% with an annual income of less than $25,000 per year) with only 29% holding private insurance. Up to 23% of the HIV-infected patients had unstable/temporary housing situations. Furthermore, 45.9% of all respondents were unwilling/unable to pay anything out

of pocket to cure their hepatitis C, which may be a significant barrier to treatment depending on insurance coverage, out of pocket copays, and availability of drug assistance programs.

Drug interactions potentially complicate HCV treatment in HIV-infected individuals, even in the era of direct-acting HCV antiviral agents (DAAs). The HCV protease inhibitors and NS5A polymerase inhibitors interact with the HIV protease inhibitors and some interact with specific HIV NNRTIS and NRTIs, including efavirenz and tenofovir (15), which in some instances necessitates changing ART. We had anticipated reluctance to switch ART, but found that the vast majority (77.1%) would consider switching ART if necessary to treat HCV. We also found a high percentage (50%) already on an ART regimen (namely with an integrase inhibitor) with less potential for drug interactions.

Despite improved tolerability of DAAs over prior interferon-containing regimens, a notable proportion of patients still reported concerns about side effects, nearly a quarter had been told by their physician that they did not need HCV treatment at the time, and some had never discussed treatment with their provider, highlighting potential provider-specific barriers to treatment. At least one prior study has shown, not surprisingly, that the likelihood of HCV treatment is highly provider dependent (16). That said, the most common answer as to why patients had not pursued treatment was that they had been waiting for new medications to arrive, although it should be noted that sofosbuvir was approved 1 month after the study opened. These are all potential points of patient and provider education with recently updated guidelines recommending treatment in all patients with chronic HCV infection (17) including in HIV/HCV where HCV treatment efficacy in coinfected patients is now comparable to monoinfected patients (18).

Interestingly, HIV/HCV-coinfected patients also demonstrated a preference for ID/HIV providers to treat their HCV. One possible explanation is that HIV-infected patients prefer care by those who better understand and can manage their HIV infection. Another possible explanation is that likely many of the HCV-monoinfected patients had never interacted with an ID physician and similarly many of the HIV/HCV-coinfected patients had never interacted with a hepatologist. A recent survey of ID physicians found that 71% believed that ID physicians should evaluate and treat HCV infections, but only a small percentage managed more than 10 patients per year (14% HIV/HCV-coinfected, 16% HCV-monoinfected) (19). Our findings further support the need for ID/HIV providers to become involved in the treatment of hepatitis C, especially among the HIV-coinfected population.

Traditional treatment barriers including drug or alcohol abuse, psychiatric diseases, unstable home situations, and lower socioeconomic status may affect initiation of treatment by providers, but our study suggests that the vast majority of patients want HCV treatment and soon, regardless of other obstacles in their lives. Cachay et al., using an inclusive HCV-treatment protocol of HIV/HCV-coinfected patients, successfully achieved SVR in 76.5% of patients with ongoing barriers to care, including drug or alcohol use, active neuropsychiatric illness, and unstable housing (20). Townsend et al. showed high HCV-treatment adherence rates (97%) with a 12-week regimen of ledipasvir and sofosbuvir, comparable between HIV/HCV-coinfected and HCV-monoinfected participants (21). These data should encourage

providers to consider HCV therapy even in those with traditional barriers to care, especially when paired with such strong patient willingness to pursue treatment.

This study benefits from its prospective enrollment of sociodemographically diverse participants from a range of clinical sites and providers. Limitations include its descriptive nature and relatively small sample size. The hepatitis C treatment options changed dramatically early in enrollment with the introduction of sofosbuvir and later with the introduction of sofosbuvir/ledipasvir, which may have impacted participant responses. Participants who responded earlier in the study period may have only had access to HCV protease inhibitor and interferon combination therapy, which may have impacted both their perceptions and provider perceptions of ease of therapy. Nevertheless, we identified potential barriers to treatment that would be independent of the available treatment options.

The large number of untreated HCV-infected individuals will result in significant HCV-related morbidity and mortality unless significant interventions to disseminate HCV treatment thwart this progression. Understanding barriers to providing HCV care is critical in this intervention. Based on this survey, most HCV-infected patients want treatment, but many need further education regarding availability of new medications and the fewer side effects associated with these medications. Providers need to be educated about the updated guidelines encouraging treatment of all patients with HCV infection. Perhaps, too, HIV/ID physicians need to become more involved in treatment of HCV-infected patients, especially those with HIV coinfection.

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Table 1

Baseline Characteristics

Variable	HIV/HCV Coinfection (n = 53)	HCV Monoinfection (n = 29)	Total (n = 82)	p-value
Age, Median (IQR)	53.5 (49–57.75)	59 (47–66)	56 (49–60)	0.29
Sex: n (%)				
Male	46 (87)	15 (52)	61 (74)	<0.01
Female	4 (8)	14 (48)	18 (22)	
Transgender	3 (6)	0 (0)	3 (4)	
Ethnicity: n (%)				
White/Caucasian	22 (42)	11 (38)	33 (40)	0.73
African American/Hispanic/Other	27 (51)	16 (55)	43 (52)	
Marital Status: n (%)				
Married/Long-term partner	11 (21)	12 (41)	23 (28)	0.05
Single/Divorced/Widowed	42 (79)	17 (59)	59 (72)	
Education: n (%)				
High School or lower	23 (43)	11 (38)	34 (41)	0.63
Some College or higher	30 (57)	18 (62)	48 (59)	
Employment: n (%)				
Employed	16 (30)	13 (45)	29 (35)	0.19
Unemployed/Other	37 (70)	16 (55)	53 (65)	
Income: n (%)				
<$25,000	40 (75)	8 (28)	48 (59)	<0.01
≥$25,000	8 (15)	18 (62)	26 (32)	
Not sure/Prefer not to say	3 (6)	2 (7)	5 (6)	
Housing: n (%)				
Stable housing	40 (75)	26 (90)	66 (80)	0.07
Temporary/Marginal	12 (23)	2 (7)	14 (17)	
County of Residence: n (%)				
Los Angeles	49 (92)	22 (76)	71 (87)	0.08
Other	3 (6)	5 (17)	8 (10)	
Insurance Coverage: n (%)				
Public	42 (82)	12 (43)	54 (68)	<0.01
Private	8 (16)	15 (54)	23 (29)	
I don't know	1 (2)	1 (3)	2 (4)	
Cirrhosis Status: n (%)				
Yes	12 (23)	8 (28)	20 (24)	0.56
No	35 (66)	17 (59)	52 (63)	
I don't know	5 (9)	4 (14)	9 (11)	
HCV Diagnosis: n (%)				
<5 years ago	18 (34)	9 (31)	27 (33)	0.74

Variable	HIV/HCV Coinfection (n = 53)	HCV Monoinfection (n = 29)	Total (n = 82)	p-value
≥5 years ago	34 (64)	20 (69)	54 (66)	
HCV Treatment: n (%)				
Yes	16 (30)	15 (52)	31 (38)	0.06
No	36 (68)	14 (48)	50 (61)	
Recreational Drug Use (Lifetime): n (%)				
THC/Tobacco	41 (77)	22 (76)	63 (77)	0.69
Non-THC	35 (66)	16 (55)	51 (62)	
None	4 (8)	4 (14)	8 (10)	
Recreational Drug Use (Active): n (%)				
THC/Tobacco	20 (38)	8 (28)	28 (34)	0.86
Non-THC	2 (4)	1 (3)	3 (4)	
None	27 (51)	18 (62)	45 (55)	
Overall Health: n (%)				
Average/Below Average	23 (43)	18 (62)	41 (50)	0.11
Above Average	30 (57)	11 (38)	41 (50)	

Abbreviations: HCV, hepatitis C virus; HIV, human immunodeficiency virus; IQR, interquartile range; THC, tetrahydrocannabinol

Table 2

Survey Responses

	Agree or Strongly Agree			
Question (n = total, HCV monoinfection, HIV/HCV coinfection)	**HIV/HCV Coinfection (%)**	**HCV Monoinfection (%)**	**Total (%)**	**p-value**
Willing to change HIV meds to treat HCV (n = 48, NA, 48)	37 (77.1)	NA	37 (77.1)	NA
Rather take IFN than change HIV meds (n = 49, NA, 49)	7 (14.3)	NA	7 (14.3)	NA
Would like to be treated for HCV at some point (n = 73, 23, 50)	47 (94.0)	21 (91.3)	68 (93.2)	0.67
Want to start HCV treatment within 1 year (n = 73, 22, 51)	46 (90.2)	15 (68.2)	61 (83.6)	0.02
Willing to wait 2 or more years to treat HCV (n = 68, 19, 49)	9 (18.4)	3 (15.8)	12 (17.6)	0.80
Willing to take meds twice a day (n = 77, 26, 51)	44 (86.3)	16 (61.5)	60 (77.9)	0.01
Willing to take meds three times a day (n = 76, 26, 50)	33 (66.0)	16 (61.5)	49 (64.5)	0.70
Willing to take more than 3 pills (n = 68, 22, 46)	20 (43.5)	10 (45.5)	30 (44.1)	0.88
Prefer IFN now rather than wait 1–2 years for FDA approval (n = 76, 25, 51)	13 (25.5)	4 (16.0)	17 (22.4)	0.35
Prefer clinical trial now rather than wait 1–2 years for FDA approval (n = 76, 25, 51)	38 (74.5)	2 (8.0)	40 (52.6)	<0.01
Willing to join a phase II trial (n = 74, 25, 49)	24 (48.98)	4 (16.0)	28 (37.8)	0.01
Willing to take medication if not studied in HIV patients (n = 50, NA, 50)	24 (48.0)	NA	24 (48.0)	NA
Willing to spend >$1000 for cure (n = 74, 24, 50)	13 (26.0)	5 (20.8)	18 (24.3)	0.63
Not willing/unable to spend anything out of pocket for cure (n = 74, 24, 50)	24 (48.0)	10 (41.7)	34 (45.9)	0.61
Prefer Hepatologist over ID Physician (n = 74, 25, 49)	12 (24.5)	22 (88.0)	34 (45.9)	<0.01
Prefer ID physician over Hepatologist (n = 74, 25, 49)	18 (36.7)	1 (4.0)	19 (25.7)	<0.01
Prefer MD over NP (n = 76, 25, 51)	35 (68.6)	20 (80.0)	55 (72.4)	0.30
Why have you not been treated? (n = 68, 19, 49)				
1. Heard that new meds are coming	15 (30.6)	5 (26.3)	20 (29.4)	0.82
2. Worried about side effects	7 (14.3)	2 (10.5)	9 (13.2)	0.74
3. Doctor told me I don't need treatment right now or can wait	11 (22.4)	5 (26.3)	16 (23.5)	0.61
4. I have never discussed treatment with my provider	2 (4.1)	2 (10.5)	4 (5.9)	0.27
5. I feel well and HCV treatment can wait	3 (6.1)	1 (5.3)	4 (5.9)	NS
6. I don't want to take more meds	0 (0)	1 (5.3)	1 (1.5)	NS
7. I am focusing on HIV right now	1 (2.0)	NA	1 (2.0)	NA
8. I don't want others to know I have HCV	1 (2.0)	0 (0)	1 (1.5)	NS
9. Doctor told me current treatments aren't safe for me	3 (6.1)	0 (0)	3 (4.4)	NS
10. Ongoing substance or alcohol use has gotten in the way	3 (6.1)	0 (0)	3 (4.4)	NS

Abbreviations: FDA, Food and Drug Administration; HCV, hepatitis C virus; HIV, human immunodeficiency virus; ID, infectious diseases; IFN, interferon; MD, medical doctor; NA, not applicable; NP, nurse practitioner; NS, not statistically significant