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Rates of HCV Treatment Eligibility Among HCV-Monoinfected and HCV/HIV-Coinfected Patients in Tertiary Care Referral Centers

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Abstract

Background—Treatment eligibility rates in patients with HCV monoinfection have not been directly compared with patients with HCV/HIV coinfection. These data are important for planning interventions to optimize HCV management.

Method—We enrolled consecutive HCV-monoinfected and HCV/HIV-coinfected subjects presenting to hepatology and HIV clinics at three academic medical centers. Data were obtained through structured subject and provider interviews and a review of medical records.

Results—Of the 399 subjects enrolled, 241 (60%) were HCV monoinfected and 158 (40%) were HCV/HIV coinfecting. HCV/HIV-coinfected subjects were less likely to have indications for treatment based on HCV RNA positivity (70.9% vs. 81.3%, $p = .04$) but were more likely to have at least one contraindication to treatment (81.6% vs. 64.9%, $p < .004$). Depression and ongoing alcohol and injection drug abuse were more common in the HCV/HIV-coinfected persons. HCV/HIV coinfecting persons were less likely to undergo liver biopsy or to ever get treatment for HCV.

Conclusions—HCV/HIV-coinfected persons are less likely to undergo a liver biopsy or be eligible for HCV therapy and are more likely to have treatment contraindications compared with HCV-monoinfected subjects. Strategies to address modifiable factors (e.g., depression, substance abuse) may enhance treatment eligibility in HCV-infected populations.

INTRODUCTION

The current standard of care for chronic hepatitis C virus (HCV) infection is pegylated interferon plus ribavirin, which can lead to viral eradication and halt or regress HCV-associated hepatic fibrosis. With this pharmacotherapy, sustained virologic response rates are 54%–56% among HCV monoinfected persons and 27%–40% in HCV/HIV-coinfected persons.^{1–5} Despite substantial improvements in HCV therapy over the last 20 years, only a minority of HCV-infected persons are ever prescribed treatment,^{6–9} perhaps due to lack of treatment eligibility, presence of contraindications to therapy, and/or perceived and real issues with adherence to the medications and follow-up visits in this population. Previous studies on HCV treatment eligibility and contraindications identified nonadherence and medical, psychiatric, and substance abuse comorbidities as the major reasons for nontreatment.^{10–15} Poor communication of information by providers and a perception of being misled, misinformed, or stigmatized were also reported by HCV-infected patients attending a specialty care clinic.¹⁶ Among HCV-infected veterans, rates of HCV treatment are lower in HCV/HIV-coinfected persons compared with HCV-monoinfected persons.¹⁰ However, there are scant data comparing treatment eligibility and contraindications directly between HCV-monoinfected and HCV/HIV-coinfected persons. These data are important for identifying the most common comorbidities that preclude HCV therapy and that should be addressed prior to treatment. In addition, such results may also suggest future interventions that could be undertaken to improve prescription rates for HCV therapy, which may help lower the incidence of HCV-associated liver failure in the HCV-monoinfected and HCV/HIV-coinfected populations. To address these issues, we compared HCV treatment eligibility in HCV-monoinfected versus HCV/HIV-coinfected persons in an academic medical center setting.

METHOD

We prospectively recruited adult HCV-monoinfected and HCV/HIV-coinfected patients referred for HCV care at the Infectious Diseases/HIV Clinics and Hepatology Clinics at the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania; University of Pennsylvania Medical Center in Philadelphia, Pennsylvania; and the University of Cincinnati Medical Center in Cincinnati, Ohio. After providing informed consent, all subjects were interviewed using a uniform structured questionnaire to gather information on demographics, risk factors for HCV and HIV, comorbid illnesses, family history, substance abuse (tobacco, alcohol, and illicit drugs), educational status, history of incarceration, and number of lifetime sexual partners. Additional laboratory and clinical data were abstracted from the subjects' medical records at the initial and most recent visits for HCV care. Liver biopsy data were retrieved from hospital computerized pathology records. HCV treatment information was gathered from patient self-report and confirmed by chart and/or pharmacy records review. All clinic patients who presented to each of the participating sites between January 2005 and November 2006 were eligible for inclusion and were recruited consecutively based on the inclusion and exclusion criteria listed above. The study was approved by the institutional review boards of the University of Pittsburgh (ClinicalTrials.gov identifier NCT00222859 for University of Pittsburgh), University of Pennsylvania, and University of Cincinnati.

HCV treatment eligibility and contraindications represented the main study outcomes. Criteria for eligibility and contraindications to HCV treatment were derived from current practice guidelines.^{17–19} The operational definitions of comorbidities and contraindications are provided in Table 1. HCV treatment eligibility and contraindications were determined at the time of initial visit for HCV care. Subjects were considered to be eligible for HCV therapy and/or have a contraindication to HCV treatment per self-report or per the medical record. Additionally, evidence of liver injury was defined as a serum alanine aminotransferase (ALT) level above

the upper limit of normal as reported by each laboratory or a liver biopsy showing at least stage 2 fibrosis.

Baseline subject characteristics were described by using means and standard deviations for continuous data and proportions for categorical data. Differences between groups were assessed by using *t* tests or Wilcoxon rank-sum tests, as appropriate, for continuous data and chi-square tests for categorical data. Analyses were conducted using STATA[®] statistical software (Stata Corp., College Station, Texas, USA).

We conducted analyses on all subjects seen at the sites as well as on the subgroup who had never received HCV treatment. Because liver biopsy is the gold standard to determine the extent of liver injury, we also determined the contraindications in the subgroup of subjects who had evidence of liver injury on a liver biopsy prior to treatment.

RESULTS

We recruited 399 subjects, 241 (60%) of whom were HCV monoinfected and 158 (40%) were HCV/HIV coinfecting. HCV/HIV-coinfecting subjects were more likely to be male, African American, and have a lower body mass index than HCV-monoinfected subjects (Table 2). In addition, HCV/HIV-coinfecting subjects were less likely to have undergone liver biopsy (43.7% vs. 71.4%, $p < .001$) or to have ever received HCV treatment (32.3% vs. 62.2%, $p < .001$) (Table 2).

HCV/HIV-coinfecting persons were less likely to have a positive HCV RNA (70.9% vs. 81.3%, $p = .03$), but within this group a similar number had evidence of liver injury (87.5% vs. 85.7%, $p = .09$) (Table 3). They were also more likely to have at least one contraindication for treatment (81.6% vs. 64.9%, $p = .004$). In particular, ongoing alcohol abuse and depression were significantly more likely to be present in the HCV/HIV-coinfecting compared with the HCV-monoinfected subjects.

When analyses were limited to subjects who had never been prescribed HCV treatment, the baseline characteristics showed the same patterns as with the full dataset. HCV/HIV-coinfecting subjects were more likely to be African American (62.6% vs. 40.7%, $p = .006$) and male (80.4% vs. 53.8%, $p < .001$) and were less likely to have undergone liver biopsy (29.9% vs. 44%, $p = .04$). As in the full dataset, HCV/HIV-coinfecting subjects were less likely to be HCV RNA positive (64.5% vs. 78.0%, $p = .04$), but rates of liver injury were not significantly different from those in HCV-monoinfected subjects (88.4% vs. 88.7%, $p = .1$). HCV/HIV-coinfecting subjects were more likely to have depression and tended to have higher rates of ongoing alcohol abuse compared with HCV-monoinfected persons. We also performed analysis limited to subjects with a liver biopsy and who had evidence of liver injury on a liver biopsy (either the inflammation or fibrosis score ≥ 2); the results were similar to the overall group, except that the differences in certain contraindications did not reach statistical significance due to a smaller sample size.

A flowchart of treatment indications and contraindications is presented in Figure 1 for the overall group and in Figure 2 for the subset who had never received any treatment.

DISCUSSION

Although effective treatment for HCV is now available and leads to eradication of chronic infection in a substantial number of treated patients, this population poses special challenges due to the higher prevalence of certain medical, psychiatric, and substance abuse comorbidities.²⁰ However, there are scant data directly comparing the rates of treatment eligibility and contraindication in HCV/HIV-coinfecting persons versus HCV-monoinfected persons in

academic medical center settings. Our study compares these two groups in an academic medical center setting.

Previous studies have shown that HCV/HIV coinfecting subjects are less likely to be prescribed HCV treatment, but the studies had a smaller sample size or the presence of treatment indications was not taken into account.^{8,10} Our results provide evidence that HCV/HIV-coinfecting subjects are less likely to be eligible for HCV therapy based on current treatment guidelines compared with HCV mono-infected subjects. The HCV/HIV-coinfecting subjects in our study had a lower rate of chronic HCV infection (defined as HCV antibody positive, HCV RNA positive) than the HCV-mono-infected group, so fewer coinfecting subjects warranted HCV therapy. This is in contrast with previous studies that have suggested that spontaneous HCV clearance occurs in only 10% of HCV/HIV-coinfecting persons and even less frequently in those with CD4 counts less than 200 cells/mm.^{3,21} The reasons for the low rate of chronic HCV infection among coinfecting subjects in our study is unclear.

Our study also demonstrates that HCV/HIV coinfecting subjects are more likely to have at least one treatment contraindication present compared with HCV-mono-infected persons. Contraindications more prevalent in the HCV/HIV-coinfecting persons in our study included depression and alcohol abuse. Depression and substance abuse have been previously reported to be more common in HCV-infected compared with HCV-uninfected persons and in HIV-infected persons compared with HIV-uninfected persons.^{7,22,23} However, our study demonstrates and compares these comorbidities directly among HCV-infected patients cared for in tertiary care referral centers. Of note, rates of contraindications to HCV therapy due to hematological abnormalities (anemia, thrombocytopenia) were less common in the coinfecting group. A possible explanation of this is referral bias, whereby persons with such toxicities are not evaluated. Additionally, HIV-infected persons may be more likely to be treated with hematopoietic growth factors for such abnormalities. We did not evaluate the use of growth factors in our study. Nevertheless, practitioners managing HCV/HIV-coinfecting patients should be aware of the more rapid declines in hemoglobin concentration in patients being treated with both ribavirin and zidovudine²⁴ and should consider switching to an alternative nucleoside analogue prior to the initiating anti-HCV therapy.

Our findings that HCV/HIV-coinfecting persons are less likely to be eligible for HCV therapy and are more likely to have treatment contraindications compared with HCV-mono-infected subjects have important clinical implications. Because chronic HCV is highly prevalent among HIV-infected patients and progresses rapidly to end-stage liver disease in the presence of HIV, antiviral therapy is critical for long-term survival of patients coinfecting with HCV/HIV. However, it is clear from our study why coinfecting patients who might be at high risk for liver failure do not receive such potentially lifesaving therapy. Methods aimed at identifying these high-risk patients prior to end-stage liver disease development (i.e., in time for patients to benefit most from treatment) may help clinicians target HCV therapy to this group and convince more HCV/HIV-coinfecting patients who need HCV treatment to accept it. In addition, our findings are important in planning interventions for optimal management of HCV infection in these groups, as they provide information about which comorbidities should be addressed aggressively if treatment rates for HCV are to be improved in these populations. The addition of dedicated mental health professionals and substance abuse counselors and treatment providers may enhance eventual treatment eligibility rates in these populations.

Our study has the strength of being able to be generalized to patient populations treated at tertiary care academic medical centers. The data were gathered prospectively to specifically answer questions about treatment eligibility and rates of prescription of treatment. Data were gathered uniformly by experienced investigators. On the other hand, a limitation of our study is that the study population constituted a referral population and is not representative of the

general population with HCV infection. Using a study population from tertiary care referral centers biases the results toward sicker patients or patients who have already been identified as needing treatment for HCV. Additionally, it is possible that patients with major contraindications were not referred for evaluation and treatment at all. We used histologic abnormalities on the liver biopsy and elevations of hepatic transaminase levels as markers of liver injury to determine eligibility for treatment. It is well known that patients with normal hepatic transaminase levels may have significant abnormalities on liver histology. Many centers have also started using noninvasive markers of liver fibrosis in the evaluation of HCV-infected patients to determine the presence of liver injury.

We chose contraindications to treatment based on the current treatment guidelines. It should be noted that not all contraindications are absolute, and indeed many may change over time (e.g., anemia may be treated, depression may resolve with or without treatment, etc.). Our definition takes the most conservative view of the treatment indications; even with such conservative estimates, we found the treatment prescription rates to be very low among eligible subjects in both HCV-monoinfected and HCV/HIV-coinfected groups. We did not analyze subjects who refused to participate in the study, because no data were gathered on those subjects.

In summary, HCV/HIV-coinfected persons are less likely to be eligible for HCV therapy and more likely to have HCV treatment contraindications. Strategies to manage modifiable comorbidities that constitute contraindications to HCV treatment may enhance treatment rates for HCV.

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Figure 1.
Flowchart of treatment eligibility and contraindications among all HCV-monoinfected and HCV/HIV-coinfected subjects in the study.

Figure 2.
Flowchart of treatment eligibility and contraindications among HCV-monoinfected and HCV/HIV-coinfected subjects in the study with no prior history of HCV treatment.

Table 1

Contraindications to HCV treatment and operational definitions.

Contraindications to HCV treatment	Operational definition
Medical Comorbidities, e.g. malignancy, coronary artery disease, chronic obstructive pulmonary disease, uncontrolled seizures, autoimmune disorders	Self report, and/or chart abstraction
Decompensated liver disease	Any of the following: <ul style="list-style-type: none"> • INR >1.2 • Prothrombin time >3 sec above ULN • Albumin <3.0 g/dl • Diagnosis of esophageal varices, ascites, hepatic encephalopathy
Severe, uncontrolled psychiatric illness	Self report, and/or chart abstraction
Ongoing alcohol abuse	Self report, and/or chart abstraction
Ongoing injection drug abuse	Self report, and/or chart abstraction
Renal failure	Serum creatinine > 1.5 mg/dl
Diabetes	Self report, and/or chart abstraction
Anemia	Hemoglobin <13.0 g/dl for men; <12.0 g/dl for women
Neutropenia	Total WBC count < 1.5×10^3 cells/mm ³
Thrombocytopenia	Platelet count < 75,000/mm ³
Heart, lung, kidney transplant	ICD-9 code or related diagnostic code
Advanced HIV disease	Most recent CD4 count <200 per mm ³
Hepatocellular carcinoma	Self report, and/or chart abstraction

Table 2

Baseline characteristics of subjects enrolled in the study.

	HCV monoinfected (n=241)	HCV-HIV coinfectd (n=158)	<i>P-value</i>
Mean age (SD)	49.7 (10.9)	48.4 (7.4)	0.18
Race			<0.001
White	65.6	36.1	
Black	30.7	58.9	
Hispanic	0.8	2.5	
Other/unknown	2.9	2.5	
% Male	58.5	81.6	<0.001
Site			0.01
Pittsburgh	51.9	42.4	
Philadelphia	21.6	34.8	
Cincinnati	26.6	22.8	
HCV genotype 1	81.9	82.9	0.82
Liver biopsy performed	71.4	43.7	<0.001
Body mass index (SD)	29.1 (5.6)	25.8 (5.5)	<0.001
Ever prescribed HCV treatment	62.2	32.3	<0.001

Note: Results are given as *N* (%) unless stated otherwise. HCV = hepatitis C virus; HAART = highly active antiretroviral therapy.

Table 3

Treatment eligibility and contraindications in HCV monoinfected vs. HCV-HIV coinfecting subjects.

	HCV monoinfected (n=241)	HCV-HIV coinfecting (n=158)	P-value
Indication for treatment	<i>n</i> (%)	<i>n</i> (%)	<i>p</i>
HCV RNA positive	196 (81.3)	112 (70.9)	.03
Evidence of liver injury among those with positive HCV RNA (either elevated ALT or stage 2 or worse liver fibrosis)	168 (85.7)	98 (87.5)	.09
Contraindications among those with indication for treatment	(<i>n</i> = 168)	(<i>n</i> = 98)	
Decompensated liver disease	27 (16.1)	15 (15.3)	.87
Coronary artery disease	9 (5.4)	4 (4.1)	.6
Diabetes	30 (17.9)	9 (9.2)	.05
Uncontrolled autoimmune disorders	14 (8.3)	12 (12.2)	.3
Depression	67 (39.9)	66 (67.4)	<.001
Recent alcohol use ^a	19 (11.4)	20 (20.4)	.05
Recent injection drug use	85 (50.6)	59 (60.2)	.13
Anemia ^b	36 (21.4)	11 (11.2)	.03
Neutropenia	1 (0.6)	0	—
Thrombocytopenia	11 (7.3)	1 (1.1)	.03
No contraindication present	59 (35.1)	18 (18.4)	.004

Note: HCV= hepatitis C virus.

^a Alcohol use more than once a week.

^b Defined as pretreatment hemoglobin ≤ 13 g/dL for men and ≤ 12 mg/dL for women.