Letters

Experience and Outcomes of Hepatitis C Treatment in a Cohort of Homeless and Marginally Housed Adults

Approximately 44% of homeless adults are hepatitis C virus (HCV)-infected.[1-5] Historically, homeless and marginally housed (HMH) adults have faced barriers to HCV treatment. New, interferon-free therapies have excellent cure rates and improved tolerability, reducing barriers for treatment.[6] To our knowledge, no published studies have documented the treatment of HMH populations with these therapies. The Boston Health Care for the Homeless Program (BHCHP) began treating HMH adults with oral agents in 2014.

Methods | We retrospectively describe the experience and outcomes of oral direct acting antiviral agents for HCV in a cohort of HCV-infected HMH adults. The study protocol was approved by the Institutional Review Board at Massachusetts General Hospital and deemed to meet Minimal Risk criteria. Patients received treatment at BHCHP, a federally qualified health center providing integrated primary care services via a patient-centered medical home approach to more than 11 000 individuals in the Boston area annually. Patients were not compensated for their participation. The HCV treatment team (a care coordinator [1.0 full-time equivalent], nurse [0.5 full-time equivalent], and 3 primary care clinicians [1 nurse practitioner, 0.25 full-time equivalent, and 2 primary care physicians—0.1 full-time equivalent combined]) provided care. Patients had an initial evaluation in which HCV testing was performed and a treatment plan was outlined. Patients were selected by clinicians based on an assessment of treatment readiness, which was based on adherence to appointments, urgency for treatment, and team collaborative decision-making. Treatment was covered by Medicare or Medicaid in all but 1 patient. At the time this cohort was treated, Massachusetts Medicaid required patients to have progressed to Metavir stage F2 prior to treatment. There were no formal payer restrictions based on sobriety. Patients received weekly calls from the care coordinator, attended follow-up appointments, and had a visit 12 weeks after treatment.

Study inclusion criteria included the following: the individual (1) must be a BHCHP patient, (2) must be at least 18 years old, (3) must have chronic HCV infection (HCV antibody positive with detectable serum HCV RNA), (4) must be enrolled in HCV treatment with oral antiviral agents between February 2014 and August 2015, and (5) must have completed follow-up by December 31, 2015. The primary outcome was sustained virologic response for 12 weeks (SVR-12) (undetectable HCV RNA ≤15 IU/mL 12 weeks after treatment completion). We compared characteristics of the 2 subsets of respondents. Statistical analyses were conducted using STATA software (version 11; StataCorp Inc).

Results | From February 2014 and August 2015, 199 HMH individuals were considered for initiation of oral therapy; 64 were
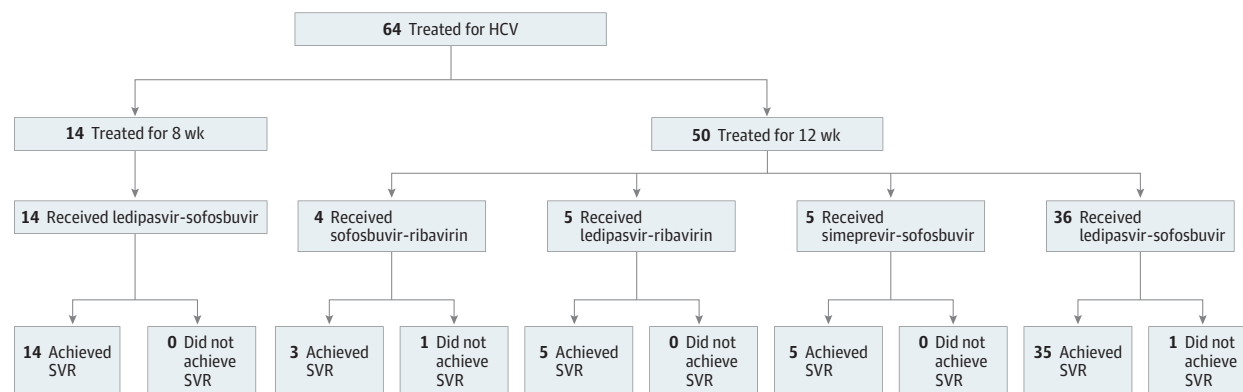
Table. Baseline Characteristics of the Cohort of 64 Hepatitis C Virus (HCV)-Infected Homeless and Marginally Housed Adults Treated With Oral Therapy

Characteristic	Sustained Virologic Response, No. (%)	
	Not Achieved (n = 2)	Achieved (n = 62)
Age, mean (SD), y	53.5 (7.8)	55.5 (7.7)
Sex		
Male	1 (50)	48 (77)
Race		
Nonwhite	1 (50)	28 (53)
Ethnicity		
Hispanic	0	45 (74)
Veteran	0	5 (8)
Education		
<High school graduate or GED	1 (50)	25 (42)
Employment		
Part-time	2 (100)	7 (12)
Full-time	0	6 (10)
Unemployed	0	20 (33)
Disability	0	27 (45)
Insured	2 (100)	60 (97)
History of incarceration	0	22 (36)
Homeless	0	26 (42)
HIV coinfected	0	29 (47)
Genotype		
Mixed	0	7 (11)
1	1 (50)	49 (79)
2	1 (50)	3 (5)
4	0	3 (5)
Fibrosis-4 value, mean (SD)	4.34	3.80 (5.84)
METAVIR stage		
F0	0	3 (5)
F1	0	22 (36)
F2	0	9 (14)
F3	0	6 (10)
F4	2 (100)	22 (35)
Reactive		
Hepatitis A virus	1 (100)	48 (83)
Hepatitis B virus	0	29 (49)
Alanine aminotransferase level, U/L, mean (SD)	98.5 (50.5)	63.5 (6.1)
HCV treatment experience	0	12 (19)
HCV treatment regimen		
Sofosbuvir-ribavirin	1 (50)	3 (5)
Simeprevir-sofosbuvir	0	5 (8)
Ledipasvir-sofosbuvir	1 (50)	49 (79)
Ledipasvir-sofosbuvir-ribavirin	0	5 (8)
History of IDU	1 (50)	46 (84)
Used drugs (including marijuana) during HCV treatment	0	16 (26)

Abbreviations: GED, General Educational Development test; HIV, human immunodeficiency virus; IDU, injection drug use.

SI conversion factor: To convert alanine aminotransferase to microkatals per liter, multiply by 0.0167.

Figure. Treatment Outcomes Stratified by Regimen

64 Treated for HCV

| 14 Treated for 8 wk | 50 Treated for 12 wk |

| 14 Received ledipasvir-sofosbuvir | 4 Received sofosbuvir-ribavirin | 5 Received ledipasvir-ribavirin | 5 Received simeprevir-sofosbuvir | 36 Received ledipasvir-sofosbuvir |

| 14 Achieved SVR | 0 Did not achieve SVR | 3 Achieved SVR | 1 Did not achieve SVR | 5 Achieved SVR | 0 Did not achieve SVR | 5 Achieved SVR | 0 Did not achieve SVR | 35 Achieved SVR | 1 Did not achieve SVR |

HCV indicates hepatitis C virus; SVR, sustained virologic response.

treated in the specified period and included in this analysis, 56 were treated outside the study period, and the rest remain untreated. Forty-nine of the 64 treated patients were male; their mean (SD) age was 55 years (7.7 years). Participant characteristics are shown in the **Table**, stratified by treatment outcome. All patients completed therapy without subspecialty referral.

Ninety-seven percent of patients (62 of 64) in this cohort achieved SVR-12. Treatment outcomes by treatment regimen are shown in the **Figure**. Only 13% reported more than 3 missed doses.

Two patients did not achieve SVR-12. Patient 1 was genotype 2 with cirrhosis, treatment naïve, HCV-monoinfected, and received only 12 weeks of sofosbuvir-ribavirin. The patient reported no missed doses of treatment, had an undetectable viral load at the end of treatment, but had a detectable viral load 12 weeks later. Patient 2 was genotype 1 with cirrhosis, treatment naïve, HCV-monoinfected, and was treated with ledipasvir-sofosbuvir for 12 weeks and missed 1 dose. The patient had a detectable viral load at end of treatment and resistance testing demonstrated H58P and L31V mutations.

Discussion | In this cohort of HCV-infected HMH adults, excellent responses to community-based treatment within a primary care program were observed with a SVR rate of 97% across genotypes and oral therapies. Viral resistance and treatment duration contributed to treatment failure in the 2 patients with treatment failure. These findings demonstrate that with a dedicated program for treating HCV in HMH adults in the primary care setting, it is possible to achieve outcomes similar to those of clinical trials and other cohorts despite significant additional barriers and competing priorities to health care faced by this population.

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