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BRIEF REPORT

Evaluation of Hepatitis C Treatment Outcomes Among Patients Enrolled in Outpatient Parenteral Antibiotic Therapy—Boston, Massachusetts, 2016–2021

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In our Boston-based outpatient parenteral antibiotic therapy (OPAT) program between 2016 and 2021, we found that a low proportion of patients with active hepatitis C virus (HCV) were prescribed HCV treatment by their OPAT provider and few achieved sustained virologic response. Clinicians should consider concurrent HCV treatment during OPAT.

Outpatient parenteral antimicrobial therapy (OPAT) programs traditionally excluded persons who inject drugs (PWID) due to concerns for line misuse, nonadherence, and difficult social circumstances [1]. However, recently there have been several successful pilot programs enrolling PWID in OPAT [2–9]. PWID are at increased risk for hepatitis C virus (HCV) infection [10–12], and treatment is critical for personal and public health benefits [13]. Direct-acting antivirals (DAAs) can achieve high rates of cure with sustained virologic response (SVR), even for PWID [14, 15]. The supportive structure of an OPAT program may present an ideal opportunity to treat HCV.

To our knowledge, no published studies examined HCV treatment among patients in OPAT. We sought to investigate HCV treatment outcomes among patients in our hospital's OPAT program, which includes PWID with HCV infection.

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METHODS

This study was performed in an academic medical center in Boston, Massachusetts, with high community rates of injection drug use. For patients with a history of recent substance use being considered for OPAT, infectious disease (ID) specialists collaborate with an addiction consult service that facilitates predischarge safety assessments and postdischarge care. Decisions regarding OPAT enrollment are made on a case-by-case basis and consider factors such as housing, social support, and engagement in substance use care. Massachusetts has few payor restrictions to DAA eligibility, and Medicaid/MassHealth has supported DAA treatment regardless of fibrosis stage since August 2016. Our OPAT program had no formal recommendation for HCV treatment during the years of this study.

Our primary aim was to identify the proportion of patients with active HCV who completed a course of DAAs and achieved SVR within 1 year of OPAT enrollment. As secondary aims, we sought to identify the proportion of patients who achieved other milestones in the HCV care cascade.

This was a retrospective cohort study evaluating patients enrolled in a first OPAT course between August 1, 2016, and February 1, 2021, with evidence of HCV. Patients were included if they were ≥18 years old at OPAT enrollment and had either laboratory-confirmed or documented history of HCV. We used our OPAT registry and our hospital's clinical data warehouse to identify patients in OPAT with evidence of HCV, including those with a positive HCV antibody, HCV RNA, or a billing code for HCV between August 1, 2011, and February 1, 2021. Each chart was reviewed by 2 ID clinicians to verify study eligibility and ascertain patient characteristics and study outcomes. All reviewers' discrepancies were reconciled to attain unanimous consensus. Patients were excluded if they did not present for scheduled ID clinic visits after hospital discharge, were the HCV-negative recipient of an HCV-positive transplanted organ, or did not yet have HCV at the time of OPAT enrollment.

Examined patient data included demographics, clinical characteristics, and substance use history. Recent substance use was defined as use within the prior 6 months. HCV status was subclassified as prior, active, or unknown: prior HCV was defined as having a history of HCV with most recent HCV RNA being undetectable; active HCV was defined as most recent HCV RNA being detectable; and HCV with unknown status was defined as history of HCV but no measured RNA at time of OPAT enrollment. SVR was defined as an undetectable HCV RNA measured ≥12 weeks after treatment completion/cessation.

Data are described as frequencies and proportions for categorical variables and as median and IQR or mean and range

for continuous variables. Analyses were conducted with SAS version 9.4 (SAS Institute).

The research protocol was reviewed by the Mass General Brigham Institutional Review Board and met criteria for exemption 45 CFR 46.104(d). As this was a retrospective analysis of existing medical records with no intervention or interactions with patients, consent was not obtained.

RESULTS

During the study period, 3295 unique patients were enrolled in OPAT, of whom 342 were flagged as potentially having HCV by database query. Of these, 118 were excluded after chart review (Supplementary Table 1). After exclusions, 224 patients (6.8% of all patients in OPAT) had evidence of active or prior HCV infection at the time of OPAT enrollment and had attended at least 1 scheduled outpatient ID visit.

Among these 224 patients, 99 (44.2%) had active HCV, 95 (42.4%) had prior HCV, and 30 (13.4%) had HCV with unknown status (Table 1). Two-thirds were male (n = 148, 66.1%). Most individuals were White (n = 203, 92.7%) and non-Hispanic (n = 207, 92.4%). Almost one-quarter of patients (n = 51, 23.3%) were experiencing homelessness. Most patients (n = 181, 80.8%) had a history of substance use, the majority of whom (n = 164, 90.6%) had a history of injection drug use. More than two-thirds (n =125, 69.1%) had recent substance use. Opioids were the most used substance (n = 166, 91.7%), and 130 (71.8%) used >1 substance. Ten (4.5%) individuals had HIV coinfection, and 36 (16.1%) had a history of hepatitis B. Cirrhosis was present in 26 (11.6%) individuals.

Among the 99 patients with active HCV, 89 (89.9%) had untreated HCV infection; 7 (7.1%) had previously treated but currently active HCV; and 3 (3.0%) were receiving DAAs at the time of OPAT enrollment. Among the 95 individuals with prior HCV, 48 (50.5%) were previously treated, and 47 (49.5%) had spontaneous clearance (Supplementary Figure 1). Of the 99 patients with active HCV, 72 (72.7%) had an HCV treatment plan documented by their OPAT clinician (Supplementary Table 2), including 19 (32.8%) who had a plan for another provider to treat and 3 (5.2%) who were already receiving HCV treatment. Of the 50 remaining patients, 14 (28%) were prescribed DAAs by their OPAT provider. Information on treatment completion was available for 13 patients, of whom 5 (38.5%) completed their treatment course. These 5 patients had HCV RNA checked 12 weeks after completing treatment; 1 additional patient did not complete a full treatment course but had his HCV RNA checked 12 weeks after stopping treatment. Of these 6 patients, 5 (83.3%) achieved SVR, and 4 (80%) achieved SVR by 1 year after OPAT enrollment. In total, 4 (8.0%) of 50 patients with active HCV and no plans for another provider to treat were prescribed DAA and achieved SVR within 1 year of OPAT enrollment (Figure 1, Supplementary Table 2)

There were 36 patients with a documented HCV plan who neither were prescribed DAAs by their OPAT provider nor had plans for another prescriber to treat HCV. Twelve patients (33.3%) did not attend follow-up visits where HCV treatment may have been offered, and 5 (13.9%) had a plan to defer HCV treatment until completion of OPAT but were never subsequently treated. Two patients (5.6%) declined treatment (Supplementary Table 2). As exploratory analyses, we examined population characteristics by treatment completion status (Supplementary Table 3) and predictors of DAA prescription (Supplementary Table 4).

DISCUSSION

In a large urban hospital with a well-developed OPAT program, OPAT providers successfully treated HCV infection in a low proportion of patients. For about one-third of those not treated, there was a documented plan for HCV treatment by an alternative provider; we did not have access to treatment outcomes for those patients. For the remaining patients not prescribed therapy, our chart review rarely elicited specific documented provider concerns, but the reasons are likely multifactorial. Possibilities include concerns for DAA side effects, drug-drug interactions, additional laboratory monitoring burden, insurance prior authorizations, and adherence to multiple new medications. Loss to follow-up may have played a significant role if patients did not attend visits in which the provider intended to prescribe DAAs. Provider stigma toward HCV and substance use may been barriers to treatment prescription. We found that a low proportion of patients declined HCV treatment when offered.

Even if prescribed therapy, less than half of patients completed their course. The majority of those with active HCV reported recent substance use, and almost all the patients who were prescribed DAAs reported recent use. Other studies have documented high SVR rates among PWID, particularly when receiving pharmacologic treatment for substance use disorder [16–22]. Our sample was too small to explore this association. Almost one-third of those with active HCV were experiencing homelessness, which may have affected retention in care [23]. Among those who were not treated, deferral of treatment and subsequent loss to follow-up were common.

The low rate of successful HCV treatment represents a missed opportunity to leverage OPAT infrastructure. We believe that the aforementioned barriers are surmountable. DAAs are well tolerated with minimal side effects, often substantially fewer than the antimicrobials used for OPAT. While drug-drug interactions are a true barrier with rifampin, most other OPAT antimicrobial agents do not have significant drug-drug interactions with DAAs. Laboratory monitoring requirements for DAA regimens are minimal, substantially less what than is typical for OPAT antimicrobials. Insurance prior

Table 1. Cohort Demographics and Characteristics

Characteristic	Patients, No. (%)			
	Total	Active HCV	Prior HCV	Unknown
No.	224	99	95	30
Age, y, median (IQR)	47 (35–60)	41 (32–53)	50 (36–62)	58 (49–63)
Sex				
Male	148 (66.1)	64 (43.2)	66 (44.6)	18 (12.2)
Female	76 (33.9)	35 (46.1)	29 (38.2)	12 (15.8)
Gender[a]				
Male	57 (25.5)	27 (47.4)	20 (35.1)	10 (17.5)
Female	37 (16.5)	13 (35.1)	15 (40.5)	9 (24.3)
Other	2 (0.9)	2 (100.0)	0 (0)	0 (0)
Not specified	128 (57.1)	57 (44.5)	60 (46.9)	11 (8.6)
Race				
White	203 (92.7)	92 (45.3)	86 (42.4)	25 (12.3)
Black/African American	8 (3.7)	2 (25.0)	3 (37.5)	3 (37.5)
Asian	2 (0.9)	1 (50.0)	1 (50.0)	0 (0)
Other	6 (2.7)	1 (16.7)	4 (66.7)	1 (16.7)
Ethnicity				
Hispanic	11 (4.9)	3 (27.3)	7 (63.6)	1 (9.1)
Not Hispanic	207 (92.4)	93 (44.9)	87 (42.0)	27 (13.0)
Unavailable	6 (2.7)	3 (50.0)	1 (16.7)	2 (33.3)
Experiencing homelessness				
Yes	51 (23.3)	29 (56.9)	18 (35.3)	4 (7.8)
No	168 (76.7)	69 (41.1)	75 (44.6)	24 (14.3)
History of substance use				
Yes	181 (80.8)	90 (49.7)	74 (40.9)	17 (9.4)
No	43 (19.2)	9 (20.9)	21 (48.8)	13 (30.2)
Recent substance use (6 mo)[b]				
Yes	125 (69.1)	69 (55.2)	50 (40.0)	6 (4.8)
No	56 (30.9)	21 (37.5)	24 (42.9)	11 (19.6)
Inpatient addiction consult[b]				
Yes	139 (76.8)	76 (54.7)	55 (39.6)	8 (5.8)
No	42 (23.2)	14 (33.3)	19 (45.2)	9 (21.4)
Injection drug use[b]				
Yes	164 (90.6)	87 (53.1)	63 (38.4)	14 (8.5)
No	17 (9.4)	3 (17.7)	11 (64.7)	3 (17.7)
Substance type[b]				
Opioids				
Yes	166 (91.7)	88 (53.0)	63 (38.0)	15 (9.0)
No	15 (8.3)	2 (13.3)	11 (73.3)	2 (13.3)
Cocaine				
Yes	117 (64.6)	64 (54.7)	47 (40.2)	6 (5.1)
No	64 (35.4)	26 (40.6)	27 (42.2)	11 (17.2)
Benzodiazepines				
Yes	38 (21.0)	19 (50.0)	19 (50.0)	0 (0)
No	143 (79.0)	71 (49.7)	55 (38.5)	17 (11.9)
Methamphetamines				
Yes	23 (12.7)	14 (60.9)	8 (34.8)	1 (4.4)
No	158 (87.3)	76 (48.1)	66 (41.8)	16 (10.1)
THC/marijuana				
Yes	54 (29.8)	32 (59.3)	19 (35.2)	3 (5.6)
No	127 (70.2)	58 (45.7)	55 (43.3)	14 (11.0)
LSD				
Yes	2 (1.1)	1 (50.0)	1 (50.0)	0 (0)
No	179 (98.9)	89 (49.7)	73 (40.8)	17 (9.5)
PCP				
Yes	1 (0.6)	0 (0)	1 (100.0)	0 (0)
No	180 (99.5)	90 (50.0)	73 (40.6)	17 (9.4)

Table 1. Continued

Characteristic	Patients, No. (%)			
	Total	Active HCV	Prior HCV	Unknown
Other				
Yes	14 (7.7)	9 (64.3)	4 (28.6)	1 (7.1)
No	167 (92.3)	81 (48.5)	70 (41.9)	16 (9.6)
Not specified				
Yes	1 (0.6)	0 (0)	1 (100.0)	0 (0)
No	180 (99.5)	90 (50.0)	73 (40.6)	17 (9.4)
Polysubstance use				
Yes	130 (71.8)	71 (54.6)	52 (40.0)	7 (5.4)
No	51 (28.2)	19 (37.3)	22 (43.1)	10 (19.6)
Pharmacologic SUD therapy[b]				
Oral/SL buprenorphine				
Yes	74 (40.9)	40 (54.1)	30 (40.5)	4 (5.4)
No	107 (59.1)	50 (46.7)	44 (41.1)	13 (12.2)
Methadone				
Yes	62 (34.3)	33 (53.2)	22 (35.5)	7 (11.3)
No	119 (65.8)	57 (47.9)	52 (43.7)	10 (8.4)
Oral naltrexone				
Yes	1 (0.6)	0 (0)	1 (100.0)	0 (0)
No	180 (99.5)	90 (50.0)	73 (40.6)	17 (9.4)
Injectable naltrexone				
Yes	4 (2.2)	2 (50.0)	2 (50.0)	0 (0)
No	177 (97.8)	88 (49.7)	72 (40.7)	17 (9.6)
Injectable buprenorphine				
Yes	2 (1.1)	2 (100)	0 (0)	0 (0)
No	179 (98.9)	88 (49.2)	74 (41.3)	17 (9.5)
Other				
Yes	17 (9.4)	11 (64.7)	6 (35.3)	0 (0)
No	164 (90.6)	79 (48.2)	68 (41.5)	17 (10.4)
Cirrhosis				
Yes	26 (11.6)	9 (34.6)	16 (61.5)	1 (3.9)
No	198 (88.4)	90 (45.5)	79 (39.9)	29 (14.7)
HIV coinfection				
Yes	10 (4.5)	3 (30.0)	6 (60.0)	1 (10.0)
No	214 (95.5)	96 (44.9)	89 (41.6)	29 (13.6)
History of hepatitis B				
Yes	36 (16.1)	14 (38.9)	20 (55.6)	2 (5.6)
No	188 (83.9)	85 (45.2)	75 (39.9)	28 (14.9)
Year of OPAT start				
2016	17 (7.6)	10 (58.8)	5 (29.4)	2 (11.8)
2017	54 (24.1)	22 (40.7)	25 (46.3)	7 (13.0)
2018	61 (27.2)	30 (49.2)	21 (34.4)	10 (16.4)
2019	41 (18.3)	19 (46.3)	18 (43.9)	4 (9.8)
2020	46 (20.5)	17 (37.0)	23 (50.0)	6 (13.0)
2021	5 (2.2)	1 (20.0)	3 (60.0)	1 (20.0)

Unknown status: confirmed HCV history but current status unknown.

Abbreviations: HCV, hepatitis C virus; LSD, lysergic acid diethylamide; OPAT, outpatient parenteral antibiotic therapy; PCP, phencyclidine; SL, sublingual; SUD, substance use disorder.

[a]No persons identified as trans or nonbinary.

[b]Among those reporting substance use.

authorizations could be facilitated by obtaining necessary HCV laboratory results or imaging while patients are hospitalized and by prescribing DAAs upon hospital discharge. Existing adherence support for OPAT antimicrobials could be extended to DAAs.

Our study had several limitations. This was a single-center study, and our findings may not be generalizable to other contexts, particularly as our OPAT program enrolls patients with recent substance use. Because of the selection process for OPAT eligibility, it is possible that our sample was biased

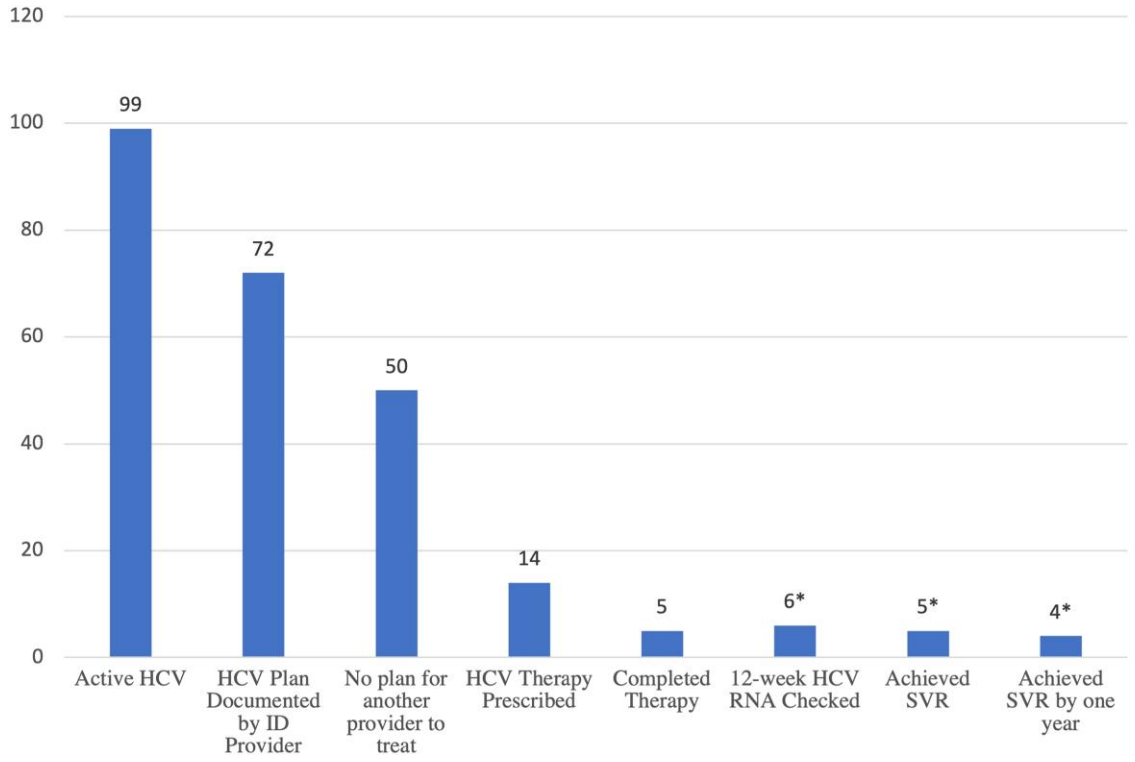

Figure 1. Hepatitis C care cascade. *One patient did not complete his 12-week HCV treatment course but achieved SVR. Abbreviations: HCV, hepatitis C virus; ID, infectious disease; SVR, sustained virologic response.

toward patients who are more likely to follow up with care. Our sample was also majority White, which reflected the overall demographics of our OPAT program but may not be generalizable to other settings. Finally, data were limited by the quality of the medical record: we may have underascertained HCV history and substance use history, and we were unable to confirm HCV treatment outcomes if another provider treated HCV.

PWID have previously been excluded from OPAT programs and from accessing HCV treatment until a period of abstinence. As these treatment programs evolve to become more inclusive of PWID, integrating HCV treatment into OPAT programs would have a substantial impact on transmission, morbidity, and mortality for this population. Future research should explore provider and patient barriers to HCV treatment and evaluate integrated treatment protocols for OPAT and HCV therapy.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Author contributions. A. G. provided significant contributions in study conception, data collection, data analysis, interpretation, manuscript drafting and revision. D. A. and F. M. S. provided significant contributions in data analysis, results interpretation, manuscript drafting, and revision. L. P. provided significant contributions in study conception, data collection, results interpretation, and manuscript revision. J. J. C. provided significant contributions in data collection, results interpretation, and manuscript revision. S. B. N., K. L. A., A. Y. K., and I. V. B. provided significant contributions in study conception, results interpretation, and manuscript revision.

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