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Successful Treatment of Chronic Hepatitis C with Triple Therapy in an Opioid Agonist Treatment Program

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Abstract

Background—People who inject drugs (PWID) constitute 10 million people globally with hepatitis C virus, including many opioid agonist treatment patients. Little data exist describing clinical outcomes for patients receiving HCV treatment with direct-acting antiviral agents (DAAs) in opioid agonist treatment settings.

Methods—In this retrospective observational study, we describe clinical outcomes for 50 genotype-1 patients receiving HCV treatment with triple therapy: telaprevir (n = 42) or boceprevir (n = 8) in combination with pegylated interferon and ribavirin on-site in an opioid agonist treatment program.

Results—Overall, 70% achieved an end of treatment response (ETR) and 62% achieved a sustained virological response (SVR). These treatment outcomes are nearly equivalent to previously published HCV outcomes shown in registration trials, despite high percentages of recent drug use prior to treatment (52%), ongoing drug use during treatment (45%) and psychiatric comorbidity (86%). Only 12% (n=6) discontinued antiviral treatment early for non-virological reasons. Four patients received a blood transfusion, and one discontinued telaprevir due to severe rash.

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Conclusions—These data demonstrate that on-site HCV treatment with direct-acting antiviral agents is effective in opioid agonist treatment patients including patients who are actively using drugs. Future interferon-free regimens will likely be even more effective. Opioid agonist treatment programs represent an opportunity to safely and effectively treat chronic hepatitis C, and PWID should have unrestricted access to DAAs.

Keywords

HCV; PWID; PWUD; IDU; injection drug users; direct-acting antiviral agents

Introduction

Hepatitis C virus (HCV) infection affects over 10 million people worldwide and is a major cause of morbidity, mortality, and healthcare expenditure (Nelson et al, 2011; Wong et al, 2000). Although people who inject drugs (PWID) have high HCV infection rates and are likely to transmit HCV by sharing drug paraphernalia, few active or recent PWID have received treatment for HCV (Grebely, 2009; Iversen, 2014; Alavi, 2014). Some of the physician reluctance to treat HCV in PWID can be attributed to concerns about poor treatment adherence associated with ongoing substance abuse or comorbid psychiatric disorders, lack of urgency to address HCV, or pessimism regarding HCV treatment tolerability or effectiveness (Davis & Rodrigue, 2001; Edlin et al, 2001). Despite these concerns, several systematic reviews provide support for using interferon and ribavirin to treat HCV in patients with active substance abuse disorders (Aspinall et al, 2012; Dimova et al, 2013; Hellard et al, 2009). These studies show that PWID respond to HCV treatment as well as non-drug using patients.

All of these studies followed PWID who initiated treatment with pegylated interferon and ribavirin. First-generation direct-acting antiviral agents (telaprevir and boceprevir) when used in combination with pegylated interferon and ribavirin (triple therapy) are associated with significantly increased proportions of sustained virological response for both treatment-naïve and treatment-experienced patients in large registration trials (Bacon et al, 2011; Jacobson et al, 2011; Poordad et al, 2011; Zeuzem et al, 2011). However, triple HCV regimens are associated with increased dosing frequency (three times daily), pill burden (up to 20 pills daily), co-administration of specific dietary requirements (e.g. 20 grams fat with telaprevir), as well as additional significant additive and novel side effects (anemia, nausea, severe rash, anal discomfort, and dysgeusia). Indeed, there have been no published real-world reports of HCV treatment outcomes in people who use drugs or opioid agonist treatment patients treated with direct-acting antiviral agents. We have previously demonstrated high percentages of SVR (40% in genotype 1) in opioid agonist treatment patients initiating treatment with pegylated interferon and ribavirin at a comprehensive on-site opioid agonist treatment program. (Litwin et al, 2009). We now describe treatment outcomes of the first fifty patients initiating treatment with triple therapy on-site within the same opioid agonist treatment program.

Methods

Treatment setting

The Division of Substance Abuse of the Department of Psychiatry and Behavioral Sciences at Albert Einstein College of Medicine operates three large methadone maintenance treatment clinics in three Bronx communities, serving approximately 3200 adults with opioid dependence. In addition to comprehensive substance abuse treatment, clinics offer medical and psychiatric care to Medicaid-insured patients choosing on-site care. Approximately 65% of all patients are HCV-antibody positive, and 50% have chronic hepatitis C.

In October 1, 2010, New York State Departent of Health funded Albert Einstein College of Medicine to continue to provide on-site hepatitis C medical, care coordination, treatment and supportive services for hepatitis C mono-infected persons at two of our Einstein clinics (n=2000). HCV evaluation and treatment were provided by internists and physician assistants with expertise in both HCV and addiction medicine, using a standardized protocol. Patient with chronic hepatitis C were referred by medical and non-medical providers, HCV program staff (coordinator or health educator), and self-referred. HCV medical care was supervised by an experienced HCV provider (AL). Of the 2000 patients, 850 patients were eligible to receive medical care on-site due to having appropriate Medicaid managed care insurance coverage, and approximately 425 patients had chronic hepatitis C. Most patients with current psychiatric comorbidities were eligible for HCV treatment. Formal psychiatric criteria were used to determine treatment ineligibility (e.g. active suicidal ideation, any psychiatric condition significantly disrupting activities of daily living, and nonadherence to psychotropic medications). HIV/HCV coinfected patients also received on-site HIV-related primary care, including highly active antiretroviral treatment when appropriate.

Staging was performed either by Fibrosure or liver biopsy. The treatment program is explained in detail in an earlier publication (Litwin et al, 2005).

All patients were treated on-site at the opioid agonist treatment program and received weekly directly administered pegylated interferon injections. Many patients were treated within a group model of treatment (Stein et al, 2012), and some were treated with modified directly observed treatment (oral medications taken at the methadone window). All patients initiating treatment with telaprevir-based regimens were provided with monthly food bags containing fatty snacks (20 grams of fat).

HCV treatment eligibility criteria

Patients with active drug or alcohol use, HIV/HCV coinfection, current psychiatric illness, and compensated cirrhosis were all eligible for HCV treatment.

Treatment

Our standardized protocol for genotype-1 infected patients called for treatment with either telaprevir or boceprevir plus once-weekly pegylated interferon in combination with twice-daily ribavirin for either 24 or 48 weeks (Ghany et al, 2011). Genotype-1 infected patients

received treatment with these regimens because it was endorsed by AASLD/IDSA, was the standard of HCV care in the United States, and covered by Medicaid. Pegylated interferon alfa-2a was dosed subcutaneously at 180 ucg weekly. The dose of ribavirin was weight-based and taken with food: 1000 mg if ≤75 kg or 1200 mg if > 75 kg. Patients received telaprevir for 12 weeks - 750 mg three times daily with high-fat food (20 grams of fat). After results of the Optimize trial were available, patients received telaprevir at a dose of 1125 mg twice daily (Buti et al, 2014). Patients starting boceprevir-based treatment received 800 mg threes time daily taken with food after a four week lead-in period of pegylated interferon alfa-2a in combination with ribavirin. Standard futility rules were applied, and patients without cirrhosis were eligible for response guided treatment if they achieved an extended rapid virological response (Ghany et al, 2011).

Key Definitions

Rapid virological response (RVR) is an undetectable viral load at week 4 after initiating either telaprevir or boceprevir.

Extended rapid virological response (eRVR) is an undetectable viral load at weeks 4 and 12 after initiating either telaprevir or boceprevir.

End of treatment response (ETR) is an undetectable viral load at the end of treatment.

Sustained virological response (SVR) is an undetectable viral load 24 weeks after completion of treatment.

Psychiatric diagnoses (depression, anxiety, psychosis, bipolar disorder, and post traumatic stress disorder) were determined by either psychiatrists or internists. Internists determined psychiatric diagnoses by structured interviews, screening tools (e.g. PHQ-9), and patient self-report. Psychiatrists determined psychiatric diagnoses by structured interviews.

Medical comorbidities included diabetes mellitus, hypertension, asthma, chronic obstructive pulmonary disease, renal disease, seizure disorder, thyroid disease, congestive heart failure, coronary artery disease, or HIV.

Recent drug use was defined as at least one positive monthly urine toxicologies (either opioids, cocaine, or benzodiazepines) in the 6 months preceding HCV treatment initiation. Patients with prescriptions in the chart for either opioids or benzodiazepines were not considered to be using drugs if toxicologies were positive for opioids and benzodiazepines, respectively.

Active drug use was defined as any positive urine toxicology within 1 month of HCV treatment initiation.

Drug use during treatment was defined as any positive urine toxicology during the period of HCV treatment.

Alcohol abuse or dependence was determined through review of most recent Addiction Severity Index-lite (administered by substance abuse counselor on intake and annually), problem list and most recent annual physical exam.

Tobacco use was determined through review of most recent annual physical exam.

Cirrhosis was defined by either liver biopsy (Ishak Stage 5 – 6) or Fibrosure (≥ 0.75).

Homelessness was determined through review of psychosocial assessment form (administered by substance abuse counselor annually).

Employment status was determined through review of psychosocial assessment form.

Adherence to both DAA (telaprevir or boceprevir) and ribavirin was assessed monthly through self-report using Visual Analogue Scale (e.g. “How much of your telaprevir or Incivek have you taken in the past 4 weeks?”) (Kalichman et al, 2009).

Data Collection and analysis

We conducted a retrospective review of medical charts using a standardized chart review instrument for all genotype-1 patients undergoing on-site HCV treatment with DAAs between January 21, 2011 and April 2, 2013. All charts were reviewed systematically including review of all laboratory data and monthly urine toxicologies. We hypothesized that the following factors may be associated with decreased proportions of SVR: IL28B (TC or TT vs. CC); cirrhosis (present vs. absent), prior treatment history (partial or non-responder vs. naïve or prior relapser); recent drug use (used within 6 months of treatment vs. used more than 6 months prior to treatment); depression (present vs. absent); anxiety (present vs. absent); drug use during treatment (any vs. none); and adherence to DAA (< 90% vs. ≥ 90%). Factors associated with SVR were identified using chi square and Fisher exact tests. Effect sizes were quantified using odds-ratio (OR). In separate multivariate models, we examined the associations of recent drug use and drug use during treatment with SVR, after adjusting for depression, IL28B, cirrhosis, and prior treatment history. This study was approved by the Albert Einstein College of Medicine Committee on Clinical Investigations.

Results

Fifty genotype-1 infected patients initiated antiviral treatment with DAAs for HCV between January 21, 2011 and April 2, 2013. Patient characteristics are summarized in Tables 1 and 2. Almost all (97%) had Medicaid-insurance, were minorities - Latinos (68%) and African Americans (28%), and had psychiatric illness (86%). The majority received telaprevir (84%) and 16% received boceprevir. Eleven patients had been previously treated unsuccessfully.

Five patients discontinued treatment during the first 12 weeks due to virologic nonresponse, and six additional patients discontinued treatment due to non-virological reasons including depression (n=1), anxiety (n=1), debilitating fatigue (n=2), incarceration (n=1), and inability to care for sick family member (n=1). Fifty-four percent of patients required erythropoietin due to anemia, and 4 patients required a blood transfusion. One patient had a severe

telaprevir-related rash during the second week of treatment, but achieved an SVR after completion with pegylated interferon and ribavirin alone.

The majority (82%) of patients had a viral load less than 43 IU/ml at 4 weeks after initiation of DAA, and 68% had a rapid virological response (RVR). Sixty percent achieved an extended rapid virological response (eRVR), 70% an end of treatment response (ETR), and 62% a sustained virological response (SVR) (Figure 1). Patients with depression, anxiety disorder, and unfavorable IL28b genotype (TC or TT versus CC) were significantly less likely to achieve SVR (Table 3). Sixty-nine percent of patients without cirrhosis (22 out of 32) and 50% of patients with cirrhosis (9 out of 18) achieved SVR. Fifty-two percent of patients used drugs within six months of initiating antiviral treatment, and 45% used drugs during HCV treatment. There was no association between recent drug use and SVR, or between drug use during treatment and SVR (Table 3). We found similar results when examining the association between each specific type of drug (opioids, cocaine, or benzodiazepines) and SVR. During HCV treatment, 27% used opioids (13 out of 49), 27% cocaine (13 out of 49), and 16% benzodiazepenes (8 out of 49). In the multivariate analysis after adjusting for depression, IL28B, cirrhosis, and prior treatment history, neither recent drug use (p=0.204) nor drug use during treatment (p=0.646) was significantly associated with SVR. Two out of the four patients who were not taking opioid agonist treatment during antiviral treatment returned to methadone maintenance treatment during the follow-up period, and both achieved an SVR. Mean adherence was high to both DAA – telaprevir or boceprevir (mean=90.1%, SD=0.15) and ribavirin (mean=91.8%, SD=0.15). There was no association between low adherence (<90%) and SVR (Table 3). No patients died during treatment or during the 6-month follow-up period.

Discussion

To our knowledge, this is the first comprehensive description of hepatitis C triple therapy treatment delivered on-site at an opioid agonist treatment program. Treatment outcomes were nearly equivalent to outcomes in HCV monoinfected patients treated in large registration trials (Bacon et al, 2011; Jacobson et al, 2011; Poordad et al, 2011; Zeuzem et al, 2011). These results are equivalent to real world results in a retrospective study from Hawaii - SVR=66%. (Akiyama et al, 2013), and higher than results from a multi-site study from New York City and Baltimore – SVR =44% (Martel-Laferriere et al, 2013). These results are equivalent to the national TARGET study that followed over 2000 patients treated with either telaprevir (SVR=60% without cirrhosis; 46% with cirrhosis) or boceprevir (SVR=50% without cirrhosis; 31% with cirrhosis). In our study, 69% of patients without cirrhosis and 50% of patients with cirrhosis achieved SVR. It’s noteworthy that these three other real-world studies did not report on patients who were actively using drugs. Our results demonstrate that PWID including those actively using drugs can be effectively treated for HCV with a model of co-located substance abuse and primary medical care. Integrated HCV care allows successful HCV treatment with complex regimens with high pill budren and significant side effects. It’s important to note that current depression and anxiety were associated with decreased proportions of SVR. It’s possible that the additional side effects related to protease inhibitors may have led to decreased effectiveness in these psychiatrically

comorbid populations. Alternatively, more intensive psychiatric care may have led to improved HCV outcomes in these patients.

Opioid agonist treatment programs, which require regular contact with patients, may promote adherence to antiviral treatment. As in the correctional setting (Moorjani et al, 2015), methadone treatment programs may also facilitate directly administered once-weekly interferon injections. HCV treatment completion is associated with improved virological outcomes (McHutchison, 2002).

There are several limitations to our study. The study is from a single institution, retrospective, and has a modest sample size. There was also a potential for selection bias given the small percentage of infected patients treated, psychiatric diagnoses were not standardized, and adherence was determined by self-report instead of pill counts or electronic monitors. We were unable to distinguish between non-injecting and injecting drug use.

With the increased costs of antiviral therapy, payers within the United States have restricted access to DAAs among people who use drugs (Barua et al, 2015). The exclusion of PWID from treatment for HCV has unjustly shaped the new era of direct-acting antiviral therapies, despite significant evidence that PWID can be successfully treated with interferon-based regimens and endorsement of the HCV treatment of PWID by multiple national and international guidelines - AASLD/IDSA, EASL, INHSU, WHO – (Davis, 2015; EASL, 2015; Grebely, 2015; WHO, 2014). We can expect that interferon-free all-oral regimens that are available now (including sofosbuvir and ribavirin; sofosbuvir and simeprevir; sofosbuvir and ledipasvir; and ombitsavir, paritaprevir, ritonavir, and dasabuvir with or without ribavirin) will be similarly associated with high percentages of SVR in PWID and opioid agonist treatment patients. Our study provides strong evidence that treatment should not be withheld from PWID and opioid agonist treatment patients despite their exclusion from large registration trials and by payers.

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Highlights

- HCV triple therapy delivered on-site at an opiate agonist treatment program
- SVR rates nearly equivalent to outcomes of patients treated in registration trials
- SVR rates equivalent to other real-world studies which did not enroll PWUDs
- There was no association between illicit drug use and SVR
- People who use drugs must have unrestricted access to direct-acting antiviral agents

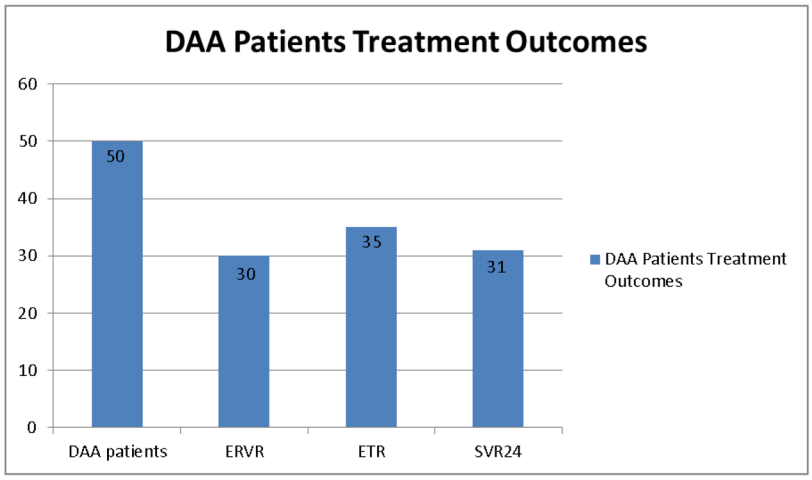

Figure 1.

Table 1

Pre-treatment Characteristics of 50 HCV-infected Patients Treated On-site with Triple Therapy at Opiate Agonist Treatment Program

Characteristic	N (%) or Mean (± SD)
Sex	
Male	31 (62)
Female	19 (38)
Race/Ethnicity	
Latino	34 (68)
African American	14 (28)
Caucasian	2 (4)
Age (years)	49.4 ± 8.7
≥ 40	41 (82)
< 40	9 (18)
Injection drug use	
Injection drug use	45 (90)
No injection drug use	5 (10)
Opiate agonist treatment	
Methadone	39 (78)
Buprenorphine	7 (14)
None	4 (8)
Recent drug use	
Used within 6 months	26 (52)
Used more than 6 months ago	24 (48)
Active drug use [+]	
Used within 1 month	7/49 (14)
Used more than 1 month ago	42/49 (86)
Tobacco	
Current smoker	41 (82)
Not current smoker	9 (18)
Psychiatric comorbidity	
Current psychiatric illness	43 (86)
No current psychiatric illness	7 (14)
Depression	
Current depression	30 (60)
No current depression	20 (40)
Anxiety disorder	
Current anxiety disorder	17 (34)

Characteristic	N (%) or Mean (± SD)
No current anxiety disorder	33 (66)
Psychotic disorder	
Current psychotic disorder	4 (8)
No current psychotic disorder	46 (92)
Bipolar disorder	
Current bipolar disorder	10 (20)
No current bipolar disorder	40 (80)
Medical comorbidity	
Current medical cormbidity	33 (66)
No medical comorbidity	17 (34)
Hypertension	
Current hypertension	21 (42)
No hypertension	29 (58)
Diabetes	
Current diabetes	13 (26)
No diabetes	37 (74)
Asthma/COPD	
Current asthma/COPD	11 (22)
No asthma/COPD	39 (78)
HIV	
HIV+	3 (6)
HIV−	47 (94)
Body Mass Index (BMI)	31.2 ± 6.2
Normal (20 – 24.9)	5 (10)
Overweight (25 – 29.9)	19 (38)
Obese (≥ 30)	26 (52)
HCV viral load	
≥ 800,000 IU/ml	26 (52)
< 800,000 IU/ml	24 (48)
HCV subtype +	
1a	24 (75)
1b	8 (25)
IL28B +	
CC	11 (22)
TC or TT	38 (78)
Prior treatment +	
Naïve or prior relapser	45 (92)
Partial or non-responder	4 (8)

Characteristic	N (%) or Mean (± SD)
Cirrhosis	
Cirrhosis	18 (36)
No cirrhosis	32 (64)
Protease inhibitor	
Telaprevir	42 (84)
Boceprevir	8 (16)
Dosing frequency	
Three times daily	41 (82)
Two times daily	9 (18)
Employment [+]	
Employed	7 (16)
Unemployed	37 (84)
Housing Status [+]	
Stable Housing	34 (77)
Unstable Housing	10 (23)

[+]missing data

Table 2

On-treatment Characteristics of 50 HCV-infected Patients Treated On-site with Triple Therapy at Opiate Agonist Treatment Program

Characteristic	N (%) or Mean (± SD)
Active drug use during treatment [+]	
Used during treatment	22/49 (45)
No use during treatment	27/49 (55)
Model of care	
Group treatment	38 (76)
Individual treatment	12 (24)
Directly observed treatment	
Pegylated interferon only	44 (88)
Pegylated interferon [+] oral meds	6 (12)
DAA Adherence [+]	90.1 ± 0.15
< 90%	13 (29)
≥ 90%	32 (71)
Ribavirin Adherence [+]	91.8 ± 0.15
< 90%	10 (21)
≥ 90%	37 (79)

[+]missing data

Table 3

SVR rates of 50 HCV-infected Patients Treated On-site with Triple Therapy at Opiate Agonist Treatment Program

Characteristic	N (%) or Mean (± SD)	SVR (n=50)	OR (95% CI) for SVR
Recent drug use			
Used within 6 months	26 (52)	15/26 (58)	Ref
Used more than 6 months ago	24 (58)	16/24 (67)	1.47 (0.46 , 4.64)
Active drug use [+]			
Used within 1 month	7/49 (14)	4/7 (57)	Ref
Used more than 1 month ago	42/49 (86)	26/42 (62)	1.22 (0.24 , 6.17)
Depression			
Current depression	30 (60)	15/30 (50)#	Ref
No current depression	20 (40)	16/20 (80)#	4.00# (1.08 , 14.81)
Anxiety disorder			
Current anxiety disorder	17 (34)	7/17 (41)#	Ref
No current anxiety disorder	33 (66)	24/33 (73)#	3.81# (1.11 , 13.07)
IL28B [+]			
TC or TT	38 (78)	20/38 (67)#	Ref
CC	11 (22)	10/11 (91)#	9.00# (1.05 , 77.4)
Prior treatment [+]			
Naïve or prior relapser	4 (8)	1/4 (25)	Ref
Partial or non-responder	45 (92)	29/45 (64)	5.44 (0.52 , 56.7)
Cirrhosis			
Cirrhosis	18 (36)	9/18 (50)	Ref
No cirrhosis	32 (64)	22/32 (69)	1.96 (0.58 , 6.56)
Active drug use during treatment [+]			
Used during treatment	22/49 (45)	13/22 (59)	Ref
No use during treatment	27/49 (55)	17/27 (63)	1.18 (0.37 , 3.73)
DAA Adherence [+]	90.1 ± 0.15		
< 90%	13 (29)	8/13 (62)	Ref
≥ 90%	32 (71)	21/32 (66)	1.19 (0.31 , 4.53)

[+]missing data