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Hepatitis C Treatment Outcomes in People Actively Using Drugs in Dallas, Texas

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Abstract

Background: Despite current AASLD/IDSA guidelines recommending treatment in all patients with chronic hepatitis C (HCV) infection with direct acting antivirals (DAA), state Medicaid programs highly restrict access in persons with recent history of illicit drug use. Programs cite concerns for poorer outcomes or higher reinfection rates. Our study describes the real world HCV treatment outcomes in people actively using drugs.

Methods: A retrospective chart review was conducted of patients who initiated treatment for chronic HCV between February 2014 and December 2015 at two Ryan White funded clinics in Dallas, Texas. Active drug use was defined as documented use within 6 months of starting HCV treatment. Outcomes, including completion of therapy and SVR-12, were compared between active drug users and non-drug users by Fisher's exact test.

Results: Sixty-four patients initiated HCV treatment with interferon-free DAAs: 62/64 (97%) were HIV-positive, 29/64 (45%) had a fibrosis score of ≥ F3 by non-invasive testing, 56/64 (88%) were treatment-naïve, and 31/64 (48%) received HCV medication through patient assistance programs. The majority of patients had HCV genotype 1a (41/64, 64%) or 1b (13/64, 20%). Active drug use was documented in 41% of patients (N=26), injection drug use in 11% of patients (N=7). Drug use, in some cases polysubstance, consisted primarily of marijuana (14/26, 54%), methamphetamine (10/26, 38%), and cocaine (5/26, 19%). At the time of review, 48 patients had passed their therapy completion date. Of these, 20/20 (100%) active drug users and 26/28 (93%) non-drug users successfully completed therapy (p=0.5). Two non-drug users discontinued therapy early due to side effects. At the time of review, 37 patients had passed their SVR-12 date. Of these, 12/15 (80%) active drug users and 19/22 (86%) non-drug users achieved SVR-12 (p=0.8). The overall rate of SVR-12 was 31/37 (84%). There were 3 failures due to relapse, and 3 patients lost to follow up. There was no evidence of HCV reinfection.

Conclusion: Patients with active drug use can achieve high rates of HCV therapy completion and SVR-12. Restrictions implemented by state Medicaid programs, which exclude such patients from receiving HCV treatment, are likely not justified.

Introduction

The majority of incident and prevalent cases of chronic hepatitis C (HCV) infection in developed countries occur among people who inject drugs. Despite the availability of highly effective direct-acting antivirals (DAAs), third party payors often restrict treatment to this population based on an expectation of poor adherence and high rate of reinfection. Nevertheless, existing data suggest the opposite- namely that people who actively use drugs, treated with pegylated interferon and ribavirin, achieve a rate of SVR comparable to that of non-drug users[1] and have a low rate of re-infection[2]. There is a paucity of data regarding treatment outcomes in active drug users treated with DAAs. Our study seeks to compare outcomes between drug users and non-drug users treated for chronic HCV at two Ryan White-funded clinics in Dallas, Texas.

1. Hilsden RJ, Macphail G, Grebely J, Conway B, Lee SS. Directly observed pegylated interferon plus self-administered ribavirin for the treatment of hepatitis C virus infection in people actively using drugs: a randomized controlled trial. Clin Infect Dis. 2013 Aug;57 Suppl 2:S90-6.
2. Grebely J, Knight E, Ngai T, Genoway KA, Raffa JD, Storms M, Gallagher L, Krajden M, Dore GJ, Duncan F, Conway B. Reinfection with hepatitis C virus following sustained virological response in injection drug users. J Gastroenterol Hepatol. 2010 Jul;25(7):1281-4.

Methods

We retrospectively reviewed the charts of 64 patients who initiated treatment for chronic HCV between February, 2014 and December, 2015 at two Ryan White funded clinics in Dallas, Texas. Demographic information, renal parameters, hepatitis C genotype and fibrosis scores, HIV status, HCV and HIV treatment regimens, funding sources, substance abuse history, and HCV treatment outcomes (completion of therapy and SVR-12) were recorded. Active drug use was defined as documented use within 6 months of initiating HCV therapy. Completion of therapy was determined by documentation of an end of therapy clinic visit or phone encounter. Baseline characteristics and treatment outcomes were compared between active drug users and non-drug users. Statistical analysis was by Mann-Whitney U test for continuous variables and Fisher's exact test for categorical variables.

Table 1. Baseline Characteristics for Total Patients

Descriptive analysis of selected characteristics for total patients (N = 64)	Frequency / Median	% / IQR with Overall Range
Age (years)	51.5	14.5 (27, 75)
Weight (kg)	78.7	23.8 (46.2, 127.4)
BMI	26.6	6.5 (16.5, 45.3)
Hgb (g/dL)	14.5	1.8 (10.2, 17.4)
Baseline CD4 count (cells/μL)[A]	470	398.0 (48, 1552)
Baseline HIV viral load (c/mL)[A]	19	49.0 (19, 319473)
Baseline HCV viral load (IU/mL)	2,076,061	5,276,919 (20608, 30034977)
Baseline SrCr value (mg/dL)	0.9	0.3 (0.6, 1.7)
Gender		
Female	14	21.9
Male	50	78.1
HIV Status		
HIV-Positive	62	96.9
HIV-Negative	2	3.1
Ethnicity		
White	24	37.5
Black	31	48.4
Hispanic	8	12.5
Asian	1	1.6
Hepatitis C Genotype		
1a	41	64.1
1b	13	20.3
2	6	9.4
3	2	3.1
4	2	3.1
HCV Fibrosis Category		
Non-advanced fibrosis (F0-F2)	35	54.7
Advanced fibrosis (≥F3)	29	45.3
HCV Treatment Status		
HCV Treatment Naïve	56	87.5
HCV Treatment Experienced	8	12.5
Substance Abuse		
Active Drug Use	26	40.6
Injection Use	7	10.9
Non-Injection Use	19	29.7
No Drug Use	38	59.4
HCV Planned Treatment Duration		
8 weeks	4	6.3
12 weeks	48	75
16 weeks	12	18.8
Funding Source of HCV Treatment		
Commercial Insurance (ACA)	1	1.6
Commercial Insurance (non-ACA)	7	10.9
Medicaid	11	17.2
Medicare Part D	14	21.9
Patient Assistance Program	31	48.4

ACA=Affordable Care Act, [A]Results documented only for HIV-positive subjects (N=62)

Figure 1. Drug Use Documented within Six Months of Starting HCV Therapy

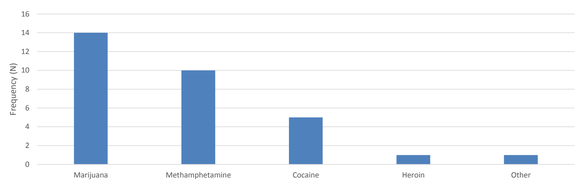


Table 2. Baseline Characteristics by Drug Use Status

Descriptive analysis of selected characteristics for total patients by drug use status (N = 64)	Active Drug Use (N=26)		No Active Drug Use (N=38)		
Variables	**Frequency / Median**	**% / IQR with Overall Range**	**Frequency / Median**	**% / IQR with Overall Range**	**P-value**
Age (years)	52	18 (32, 65)	52	10 (27, 75)	0.4
Weight (kg)	166	46 (115, 253)	180.8	56 (101.6, 280.2)	0.1
BMI	25.2	6.1 (18.6, 35.4)	26.9	6 (16.5, 45.3)	0.5
Hgb (g/dL)	14.3	1.7 (11.9, 16.7)	14.9	2.2 (10.2, 17.4)	0.3
Baseline CD4 count (cells/μL)[A]	537	521 (48, 1552)	460	313 (56, 981)	0.6
Baseline HIV viral load (c/mL)[A]	19	311 (19, 319473)	19	24.5 (19, 2250)	0.3
Baseline HCV viral load (IU/mL)	3,575,041	8,256,745 (32125, 23060262)	1,617,850	4,601,817 (20608, 30034977)	0.3
Baseline SrCr value (mg/dL)	0.9	0.2 (0.6, 1.4)	0.8	0.4 (0.6, 1.7)	0.6
Gender					
Female	4	15.4	10	26.3	0.4
Male	22	84.6	28	73.7	
Ethnicity					
White	8	30.77	16	42.11	0.5
Black	13	50	18	47.4	
Hispanic	4	15.4	4	10.5	
Asian	1	3.9	0	0	
Hepatitis C Genotype					
1a	18	69.2	23	60.5	0.3
1b	3	11.5	10	26.3	
2	2	7.7	4	10.5	
3	1	3.9	1	2.6	
4	2	7.7	0	0	
HCV Fibrosis Category					
Non-advanced fibrosis (F0-F2)	15	57.7	20	52.6	0.8
Advanced fibrosis (≥F3)	11	42.3	18	47.4	
HCV Treatment Status					
Treatment Naïve	24	92.3	32	84.2	0.5
Treatment Experienced	2	7.7	6	15.8	

Table 3. HCV Treatment Details by Drug Use Status

Descriptive analysis of selected characteristics for total patients by drug use status (N = 64)	Active Drug Use (N=26)		No Active Drug Use (N=38)		
	Frequency / Median	**% / IQR with Overall Range**	**Frequency / Median**	**% / IQR with Overall Range**	**P-value**
HCV Medication					
SOF/LDV	14	53.9	21	55.3	0.9
SOF/LDV + RBV	1	3.9	0	0	
SOF + DCV	1	3.9	2	5.3	
SOF + SIM	0	0	1	2.6	
SOF + RBV	5	19.2	6	15.8	
PrOD	1	3.9	2	5.3	
PrOD + RBV	4	15.4	6	15.8	
HCV Planned Treatment Duration					
8 weeks	1	3.9	3	7.9	0.9
12 weeks	20	76.9	28	73.7	
16 weeks	5	19.2	7	18.4	
Funding Source of HCV Treatment					
Commercial Insurance (ACA)	0	0	1	2.6	0.2
Commercial Insurance (Non-ACA)	2	7.7	5	13.2	
Medicaid	4	15.4	7	18.4	
Medicare Part D	3	11.5	11	29	
Patient Assistance Program	17	65.4	14	36.8	

SOF=sofosbuvir, LDV=ledipasvir, RBV=ribavirin, DCV=daclatasvir, SIM=simeprevir, PrOD=paritaprevir/ritonavir/ombitasvir/dasabuvir

Figure 2. Rate of HCV Therapy Completion by Drug Use Status

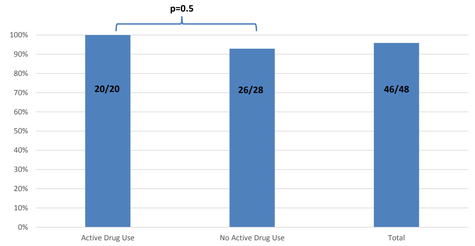
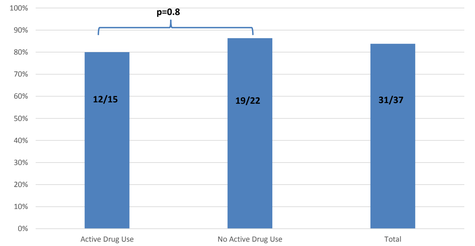


Figure 3. Rate of SVR-12 by Drug Use Status



Results

Sixty-four patients initiated HCV treatment with interferon-free DAAs (Table 1). Active drug use was documented in 40.6% (N=26) and injection drug use in 10.9% (N=7). Drug use consisted primarily of marijuana (14/26), methamphetamine (10/26), and cocaine (5/26) as shown in Figure 1. There were no significant differences in baseline characteristics or HCV treatment regimens between active drug users and non-drug users (Tables 2 and 3). Outcomes were similar between the two groups. Data were available for 48 patients who had passed their expected therapy completion date. Of these, 100% (20/20) active drug users completed therapy compared to 93% (26/28) non-drug users, p=0.5 (Figure 2). Two non-drug users discontinued therapy early due to side effects. Data were available for 37 patients who had passed their expected SVR-12 date. Of these, 80% (12/15) active drug users achieved SVR-12 compared to 86% (19/22) non-drug users, p=0.8 (Figure 3). Three patients relapsed (2 active drug users, 1 non-drug user) and three were lost to follow up (1 active drug user, 2 non-drug users). There was no evidence of HCV re-infection.

Conclusion

- Patients with active drug use can achieve high rates of HCV therapy completion and SVR-12
- These results are consistent with previously conducted prospective clinical trials in the pre-DAA era as well as the recently published C-EDGE CO-STAR trial
- Restrictions implemented by state Medicaid programs and other third party payors which exclude patients with active drug use from receiving treatment are inconsistent with published data.