The Care Cascade of Hepatitis C Management with Direct-Acting Antivirals in HIV-Infected Individuals

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BACKGROUND

- In the United States, there are about 3.2 million people with hepatitis C virus (HCV) and 1.1 million people with human immunodeficiency virus (HIV), of which up to 30% are co-infected with HCV [1, 2].
  - Certain groups are at higher risk for co-infection (e.g., intravenous drug users) due to similar routes of transmission and higher prevalence [2].
- Co-infection leads to increased morbidity with decreased HCV clearance, accelerated liver fibrosis, and higher risk for decompensation and liver-related mortality [3, 4].
- In the era of HCV interferon-based therapy, sustained viral response (SVR) was often low due to major barriers to starting HCV treatment. These included drug adverse effects, poor tolerability, poor HIV control, low effectiveness, psychiatric illness, race, limited knowledge about treatment, infrastructure limitations, and insurance/cost [5, 6].
- New HCV direct-acting antivirals (DAAs) offer improved tolerability and high SVR but barriers including insurance/cost, race, and engagement in care have limited access to these medications [7, 8].
- Little data exists on barriers to care and DAA access in the HIV/HCV co-infected population. This study aims to identify areas for possible intervention in this cohort.

METHODS

- Retrospective chart review of all HIV-infected patients with active chronic HCV infection at the Washington University Infectious Diseases (WUID) clinic in St. Louis, Missouri.
- Inclusion criteria: age 18 years or older and ≥1 follow up visit in WUID clinic between January 1, 2014 and December 31, 2015.
- Exclusion criteria: clearance of HCV spontaneously or from prior interferon-based treatment, lost to follow up, death before start of study period, positive HCV antibody without follow up HCV RNA.
- Demographics, insurance information, comorbidities, baseline laboratory data, HIV status, liver fibrosis stage (from imaging, biopsy, or biomarker testing) were collected. Model for End-Stage Liver Disease (MELD) was calculated for all patients with cirrhosis.
- Statistical analysis with Chi-square/Fisher test and Mann-Whitney test.
- Definitions:
  - *Chronic HCV infection:* detectable HCV RNA for ≥ 6 months
  - *Lost to follow up*: no follow up visit between January 1, 2014 and December 31, 2015.

RESULTS

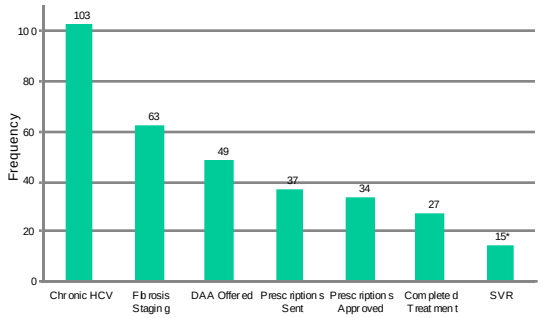
Table 1. Baseline characteristics (n=103)

Variable	Mean ± SD or Freq (%)
Mean Age	51 y ± 9.0
White	27 (26.2%)
African American	76 (73.8%)
Male	85 (82.5%)
Substance Abuse	22 (21.4%)
Psychiatric Illness	57 (55.3%)
Genotype 1	88 (85.4%)
Cirrhosis	27 (26.2%)
Mean MELD	10 ± 4.9
Mean Time to Initial Decision	9.8 d ± 11.0
Mean Time to Final Decision	16.9 d ± 24.9

Table 2. Key factors related to offering DAA

Variable		DAA Offered	P value
Insurance	Y	49/97 (50.5%)	0.028
	N	0/6 (0.0%)	
Substance Abuse	Y	2/22 (9.1%)	<0.001
	N	47/81 (58.0%)	
Psychiatric Illness	Y	28/57 (49.1%)	0.726
	N	21/46 (45.7%)	
Suppressed HIV >6 Mos	Y	45/71 (63.4%)	<0.001
	N	4/32 (12.5%)	
Prior HCV Treatment	Y	17/23 (73.9%)	0.004
	N	32/80 (40.0%)	
Fibrosis Testing	Y	38/63 (60.3%)	0.001
	N	11/40 (27.5%)	
Cirrhosis	Y	14/27 (51.9%)	0.604
	N	35/76 (46.1%)	

Figure 1. Care cascade of HCV/HIV co-infected patients at WUID clinic



*Twelve week post-treatment labs and data were still pending for 11 patients at the time of data collection. One patient did not achieve SVR.

Table 3. Reasons for not offering DAA* (n=54)

Reason	Freq (%)
Active substance abuse	19 (35.2%)
Other comorbid condition	6 (11.1%)
Unclear reason	9 (16.7%)
Uncontrolled HIV	12 (22.2%)
Depression	13 (24.1%)
Patient not interested	2 (3.7%)
Renal disease	3 (5.6%)
Newly diagnosed	3 (5.6%)

*Each patient may have more than one reason for not being offered DAA.

CONCLUSIONS AND DISCUSSION

- Many co-infected patients may not be offered HCV treatment because of substance abuse and uncontrolled HIV.
- Approval times in our study appear to be less significant of a barrier than previously reported.
- Many barriers appear to be due to provider perceptions which represent an area of further investigation and may represent a possible point of intervention.
- Addressing these barriers to HCV treatment may increase the number of patients offered therapy and may improve real-world SVR with DAAs.
- Limitations: single center, demographics, small sample size precluding multivariate analysis.

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