Outcome of Chronic Hepatitis C infection in HIV Co-infected with Sofosbuvir containing Regimens in HIV Primary Care Setting with Integration of New York State Department of Health Funding Support

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Abstract

Background: To support and enhance the capacity to provide hepatitis C medical care and treatment through the integration of services into our Ryan White Part C funded Human Immunodeficiency Virus (HIV) primary care setting, additional grant funding from New York State Department of Health provided partial salary support for a hepatologist, hepatitis C nurse coordinator and peer advocate. A 2-year retrospective study was done to determine clearance of Hepatitis C Virus (HCV) 12 weeks after completion of HCV treatment in HIV co-infected patients.

Methods: A retrospective review of outpatient medical records was done of HIV/HCV co-infected patients who were initiated on HCV therapy from January 2014 to December 2015. All had suppressed HIV viremia prior to HCV treatment initiation. HIV/HCV care was provided by their usual medical providers who consisted of 4 Infectious Disease physicians, 2 internists and 1 physician's assistant. Referral to hepatologist and medication review by HIV/HCV pharmacist was at the discretion of primary provider. Age, gender, ethnicity, HCV genotype, prior HCV treatment regimen, change in antiretroviral regimen if needed for drug-drug interaction and HCV treatment outcome was collected and tabulated.

Results: 97 patients were initiated on HCV treatment during this 2 year period. 78 were male and 19 female. 42% were Caucasian, 43% black and 15% Hispanic. Age ranged from 31 to 71 years. 69% had advanced liver fibrosis. 57% had genotype 1a, 27% genotype 1b and 5% had genotype 1 which could not be further differentiated. 6% had genotype 2, 4% genotype 3 and 1% genotype 4. 46% were prior treatment experienced which was pegylated interferon with ribavirin (PEG-RIBA) in 69%, PEG-RIBA and protease inhibitor in 25%, simeprevir with sofosbuvir in 4% and PEG-RIBA and sofosbuvir in 2%. 39% were referred for evaluation by hepatologist. Antiretroviral regimen was changed in 35% to facilitate HCV treatment. All 97 received sofosbuvir containing regimen; ledipasvir-sofosbuvir 73%, sofosbuvir-ribavirin 10%, simeprevir-sofosbuvir 7%, PEG-RIBA-sofosbuvir 5%, ledipasvir-sofosbuvir-ribavirin 2%, simeprevir-sofosbuvir-ribavirin 2%. 12 weeks post treatment HCV RNA was available for 90 with 92% cure rate.

Conclusion: HCV therapy can be safely integrated into HIV primary care setting with 12 week sustained virologic response rates similar to clinical trials.

Background

To support and enhance capacity to provide hepatitis C medical care and treatment through the integration of services into our Ryan White Part C funded Human Immunodeficiency Virus (HIV) primary care setting, additional grant funding was obtained from New York State Department of Health (NYDOH) from October 2010 to March 2015 for HIV/HCV Co-infection care and treatment services. This provided salary support for part time hepatologist, hepatitis C nurse coordinator, peer advocate, data analyst, project manager and mental health referral services if needed. A 2-year retrospective study was done to determine 12 week sustained viral response (SVR12) after completion of HCV therapy in HIV co-infected.

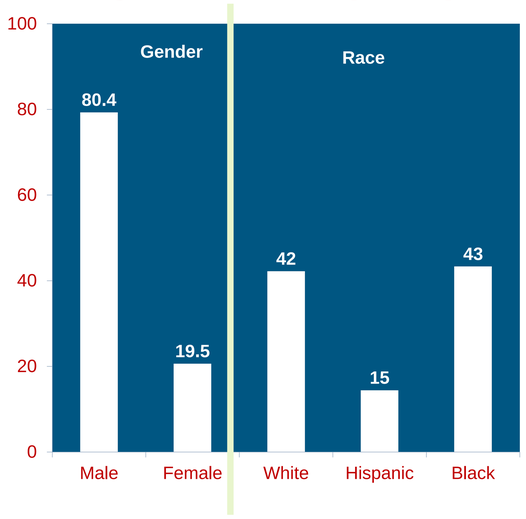
The aim of the study was to determine safety and efficacy of Sofosbuvir containing regimens in HIV/HCV co-infected in a Ryan White HIV care clinic.

Methods

A retrospective review of outpatient medical records was done of HIV/HCV co-infected patients who were initiated on HCV therapy from January 2014 to December 2015. All had suppressed HIV viremia prior to HCV treatment initiation. HIV/HCV care was provided by their usual medical providers who consisted of 4 Infectious Disease physicians, 2 internists and 1 physician's assistant. Referral to hepatologist and medication review by HIV/HCV pharmacist was at the discretion of primary provider.
Age, gender, ethnicity, HCV genotype, prior HCV treatment regimen, change in antiretroviral regimen if needed for drug-drug interaction and HCV treatment outcome was collected and tabulated.

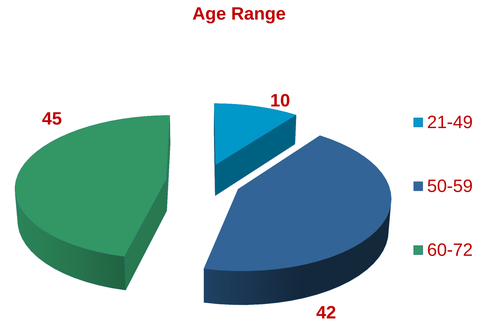
Results

Gender and Race of Subjects, Percent (n=97)



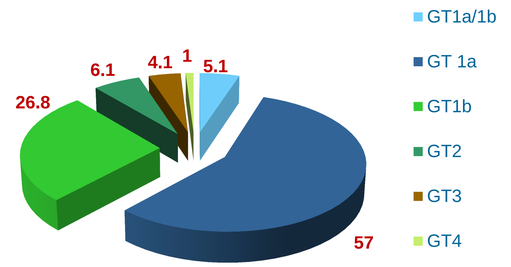
Fibrosis	N (%)
Advanced Fibrosis (Fibrosure F3-4, fibrospect > 41 or cirrhosis)	67 (69%)
Early fibrosis (F0-2)	29 (29.8%)
No staging done	1

Percent of Patients in Each Age Group, n=97



Prior HCV Treatment	N (%)
NAÏVE	52 (53.6%)
PRIOR TREATMENT EXPERIENCED	45 (46.4%)
PEG-RIBA	**31 (31.9)**
PEG-RIBA+NS3 PI	11 (11.3)
SIM-SOF	2 (2.06)
PEG-RIBA-SOF	1 (1.03)

Percentage of Patients with each HCV Genotype, n=97



Evaluation by Hepatologist: 38/97 = 39%

HCV Treatment Regimen	N =97(%)
Led-sof	71 (73.1)
Led-sof-riba	2 (2.06)
Sim-sof	7 (7.29)
Sim-sof-riba	2 (2.06)
Sof-riba	10 (10.3)
Peg-riba-sof	5 (5.15)

Sofosbuvir-based treatment for all 97

Characteristics of 7 patient with HCV treatment failure

Genotype	Prior HCV Rx	Fibrosis	HIV Rx	HCV regimen	Duration of Rx Received	Adherence	PPI	Review by Hepatologist	Pretreatment HCV Log IU/ml	Virologic Failure
1b	PEG-RIBA	F1	TDF/FTC+ NVP	Led-sof	12 weeks	Y	N	N	7.09	Nonresponder
1b	PEG-RIBA	F4	ABC+ETR+ RAL	Led-sof	24 weeks	Y	Omeprazole 20mg 12hrs apart	Y	4.39	Relapse
1a	PEG-RIBA	F4	EFV+RAL+ ABC/3TC	Led-sof	24 weeks	Y	Omeprazole 20mg 12 hrs apart	Y	7.39	Relapse
1a	PEG-RIBA-TELAPREVIR	F1	AZT/3TC/ ABC+ TDF+RAL	Led-sof	8 weeks	N	N	N	6.70	Lost to care
1b	Naïve	F4	TDF/FTC/ RPV+RAL	Led-sof	12 weeks	Y	N	Y	5.78	Nonresponder
1a	PEG-RIBA	F4	DRV/r+RAL+ MVC	Led-sof-Riba	12 weeks	Y	N	Y	6.76	Relapse
1b	PEG-RIBA	F4	TDF/FTC+ DTG	Led-sof	12 weeks	Y	N	N	5.82	Relapse

Conclusion

- **Antiretroviral regimen changed in 35%.**
- **All had suppressed HIV RNA.**
- **92% achieved 12 week HCV SVR.**
- **HCV therapy can be safely integrated and provided at Ryan White HIV clinics to scale up HCV treatment.**

Acknowledgement

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