Baseline Mental Health Disease and Hepatitis C:
Impact on Sustained Virologic Response and Adherence with Interferon-Free Therapy

[1]Jack Masur, [1]Lydia Tang, [1] Amy Nelson, [1,2,3]Anu Osinusi, [2,5]Anita Kohli, [4]Michael A Polis, and [1, 4]Shyam Kottilil

(1) Institute of Human Virology, University of Maryland School of Medicine, Baltimore, MD; (2) Critical Care Medicine Department, National Institutes of Health, Bethesda, MD (3) Gilead Sciences Inc, CA. (4) Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD; (5) Clinical Research Directorate/Clinical Monitoring Research Program, Leidos Biomedical Research, Inc. (formerly SAIC-Frederick, Inc.), National Laboratory for Cancer Research, Frederick, MD

BACKGROUND

- 30-44% of all patients with hepatitis C virus (HCV) have an active psychiatric or drug-use disorder
- Mental health disorder (MHD) continues to be a significant barrier to HCV treatment
- Interferon (IFN)-free directly-acting antiviral (DAA) regimens are achieving sustained virologic response (SVR) rates >90% for both treatment naïve patients and those who previously failed IFN-based therapy
- The impact of MHD on adherence and rates of SVR with IFN-free regimens has not been previously reported

AIM

- Determine impact of MHD on IFN-free HCV therapy as measured by cure (SVR12) rates and adherence

METHODS

- 45 patients with MHD were identified from 3 NIAID clinical trials
  - SPARE (SOF/RBV; 24 weeks): HCV monoinfected, n=23
  - SYNERGY A (SOF/LDV; 12 weeks): HCV monoinfected, n=7
  - ERADICATE (SOF/LDV; 12 weeks): HCV-HIV coinfected, n=15
- Evaluate primary efficacy and adherence in participants with and without MHD
- Primary efficacy: SVR12, defined as undetectable HCV RNA 12 weeks post-treatment
- Measures of adherence
  - Pill count
    - Percentage of patients who completed treatment with 3 or less missed pills
    - Average number of SOF/LDV pills (SYNERGY A and ERADICATE)
  - Attendance at study visits (SPARE)
  - Drug levels of SOF and its metabolite GS-331007 were obtained on 25 participants in SPARE

RESULTS

- There was no statistically significant difference between MHD individuals and non-MHD individuals with rates of SVR and all measures of adherence (See Figures 1-4)

Table 1. Baseline Characteristics of All Study Participants

	SPARE (n=60)	SYNERGY A (n = 20)	ERADICATE (n = 50)	p-value
Age – mean ± SD	55 ± 4	57 ± 8	59 ± 8	0.13
Male gender – no (%)	37 (62)	14 (70)	37 (74)	0.37
Race or ethnicity – no (%)				0.93
White	8 (13)	4 (20)	7 (14)	---
Black	50 (83)	16 (80)	42 (84)	---
Hispanic	2 (3)	1 (5)	1 (2)	---
HCV GT 1 subtype – no (%)				0.12
1A	42 (70)	11 (55)	39 (78)	---
1B	18 (30)	9 (45)	10 (20)	---
HIV +	0 (0)	0 (0)	50 (100)	<0.0001

Table 2. Baseline Characteristics of Participants with Mental Health Disorder

	SPARE (n=23)	SYNERGY A (n = 7)	ERADICATE (n = 15)	p-value (p=0.66)
Age – mean ± standard deviation	54 ± 6	52 ± 10	56 ± 8	0.44
Male gender – no (%)	14 (61)	5 (71)	9 (60)	0.86
Race or ethnicity – no (%)				0.68
White	4 (17)	2 (29)	2 (13)	---
Black	19 (83)	5 (71)	13 (87)	---
Hispanic	0	0	0	---
HCV GT 1 subtype – no (%)				0.46
1A	18 (78)	4 (57)	12 (80)	---
1B	5 (22)	3 (43)	3 (20)	---
HIV +	0 (0)	0 (0)	15 (100)	<0.0001
Mental Health Disorder				
Depression	14 (61)	4 (57)	8 (53)	0.89
Anxiety	4 (17)	3 (43)	1 (7)	0.12
Bipolar Disorder	4 (17)	3 (43)	5 (33)	0.32
PTSD	2 (7)	1 (14)	3 (20)	0.60
Schizophrenia	0	1 (14)	0	---

RESULTS

Figure 1. SVR12 Achieved
(SPARE 60.9% vs. 67.6%, *p=0.78*)

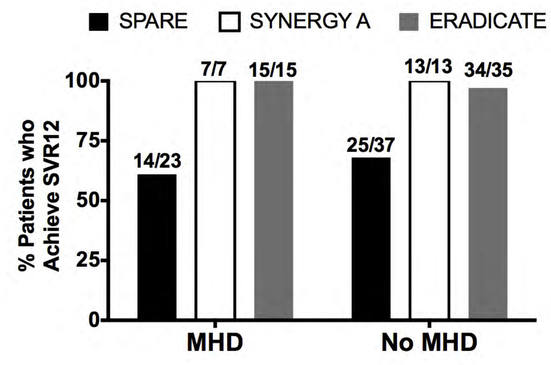


Figure 2. Patients with No More than 3 Missed Doses
(ERADICATE *p=0.70;* SYNERGY A *p=0.11*)

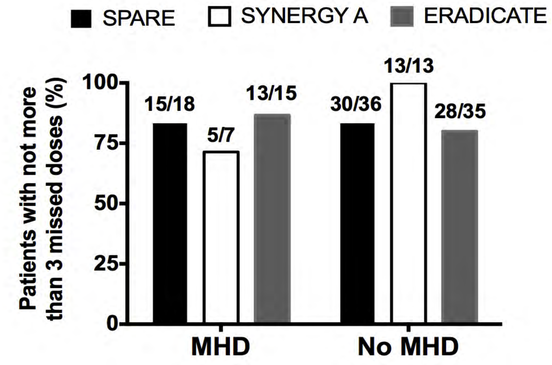


Figure 3. Completed Visits
(SPARE only)

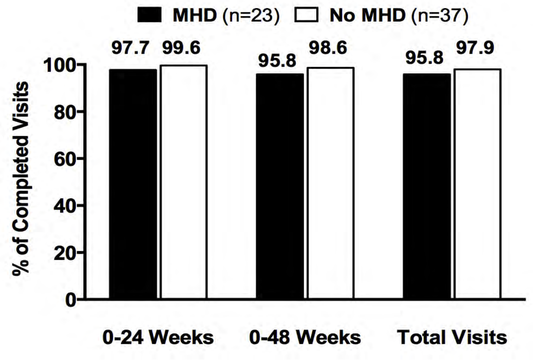
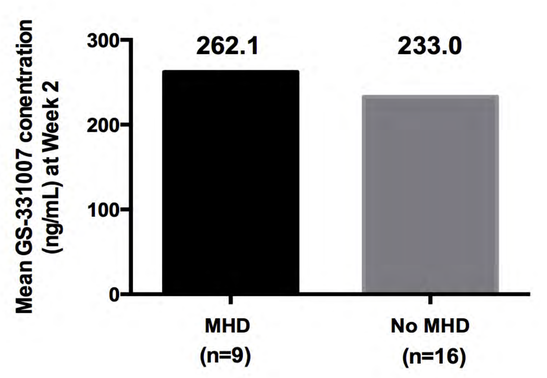


Figure 4. GS-331007 Concentration at Week 2
(SPARE only; *p=0.72*)



CONCLUSIONS

- Patients with baseline mental health disorder were engaged and treated successfully with directly-acting antivirals for hepatitis C infection in these clinical trials
- Further large-scale studies exploring improving access to IFN-free HCV therapies for patients with mental health disorder and identifying patient characteristics which necessitate adherence interventions are indicated

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