


REPORTING ON EASL 2017
**ADVANCES IN CHRONIC HEPATITIS C:
MANAGEMENT AND TREATMENT**
**COMPREHENSIVE EXPERT REVIEW
AND DISCUSSION OF KEY PRESENTATIONS**

AN INDEPENDENT CME ACTIVITY JOINTLY PROVIDED BY POSTGRADUATE INSTITUTE FOR MEDICINE AND VIRALD, INC.
THE COVERAGE IS NOT SANCTIONED BY THE CONFERENCE ORGANIZERS AND IS NOT AN OFFICIAL PART OF THE CONFERENCE PROCEEDINGS.

Treatment of Persons Who Inject Drugs

Mark Sulkowski, MD
Professor of Medicine
Johns Hopkins University School of Medicine



REPORTING ON EASL 2017
**ADVANCES IN CHRONIC HEPATITIS C:
MANAGEMENT AND TREATMENT**
**COMPREHENSIVE EXPERT REVIEW
AND DISCUSSION OF KEY PRESENTATIONS**

AN INDEPENDENT CME ACTIVITY JOINTLY PROVIDED BY POSTGRADUATE INSTITUTE FOR MEDICINE AND VIRALD, INC.
THE COVERAGE IS NOT SANCTIONED BY THE CONFERENCE ORGANIZERS AND IS NOT AN OFFICIAL PART OF THE CONFERENCE PROCEEDINGS.

The PREVAIL Study: Intensive Models of HCV Care for People who Inject Drugs

A.H. Litwin, L. Agyemang, M.J. Akiyama, B.L. Norton, M. Heo, Y. Ning, G. Umanski, J.H. Arnsten

Abstract PS-130

PREVAIL Study: Design and Baseline Characteristics

- RCT of HCV treatment for PWIDs with genotype 1 on OAT, including those actively using drugs
 - October 2013 to May 2016
- 158 Participants were randomized to one of three models of HCV care delivered on-site in an OAT program and 150 started DAAs
 - Directly observed treatment (n=51)
 - Group medical visit (n=48)
 - Individual treatment as usual (TAU, n=51)
 - HCV regimens administered as per AASLD/IDSA guidelines

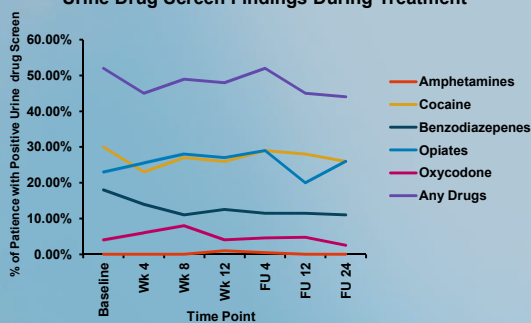
Regimen	Duration (Wks)	Start Date
TVR/PEG/RBV	24 – 48	10/2013
SOF/RBV ± PEG	12 – 24	12/2013
SOF + SMV	12 – 24	8/2014

	Individual (n=51)	Group (n=48)	DOT (n=51)	Total (n=150)
Age (years)	51.0 (10.3)	51.2 (10.6)	51.4 (10.3)	51.2 (10.6)
Male	32 (62.8)	32 (66.7)	33 (64.7)	97 (64.7)
Homeless	15 (29.4)	10 (20.8)	9 (17.7)	34 (22.7)
Drug screen				
Any drug	28 (54.9)	24 (50.0)	25 (49.0)	77 (51.3)
Opiates	11 (21.6)	14 (29.2)	12 (23.5)	37 (24.7)
Cocaine	16 (31.4)	11 (22.9)	17 (33.3)	44 (29.3)
Benzos	10 (19.6)	4 (8.3)	9 (17.7)	23 (15.3)
Methadone	49 (96.1)	47 (97.9)	51 (100)	147 (98.0)
Alcohol to intoxication	12 (23.5)	11 (22.9)	13 (25.5)	36 (24.0)
Genotype 1a	44 (86.3)	41 (85.4)	43 (84.3)	128 (85.3)
Cirrhosis	10 (19.6)	16 (33.3)	15 (29.4)	41 (27.3)
DAA Regimen				
SOF/LDV	35 (68.6)	38 (79.2)	31 (60.8)	104 (69.3)
SOF/SMV	4 (7.8)	2 (4.2)	5 (9.8)	11 (7.3)
SOF/RBV	5 (9.8)	3 (6.3)	9 (17.7)	17 (11.3)
SOF/RBV/PEG	7 (13.7)	3 (6.3)	5 (9.8)	15 (10.0)
TVR/RBV/PEG	0 (0)	2 (4.2)	1 (2.0)	3 (2.0)

Litwin A, et al. 52nd EASL; Amsterdam, Netherlands; April 19-23, 2017. Abst. PS-130.

PREVAIL Study: Intensive Models of HCV Care for People who Inject Drugs

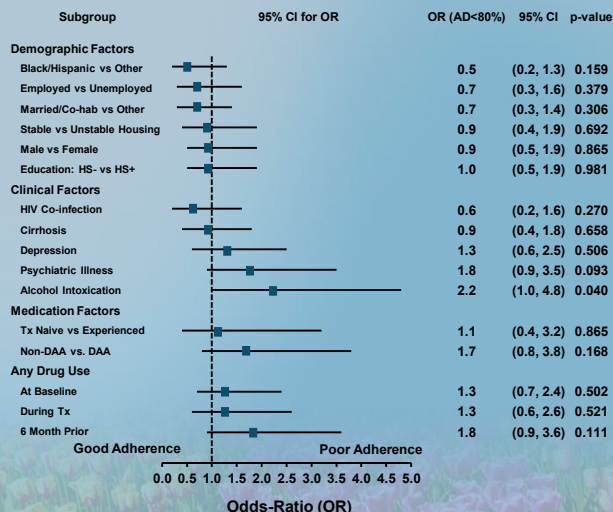
Urine Drug Screen Findings During Treatment



Predictors of Adherence < 80%

Predictor	OR	95% CI	P-Value
Recent Drug use (6 Months Prior)	1.6	0.7 – 3.6	0.22
Any Drug Use at Baseline	1.2	0.6 – 2.5	0.55
Any Drug Use During HCV Treatment	1.1	0.5 – 2.5	0.80

Overall Adherence: DOT (75.0%), Group (61.4%); Individual (62.4%)

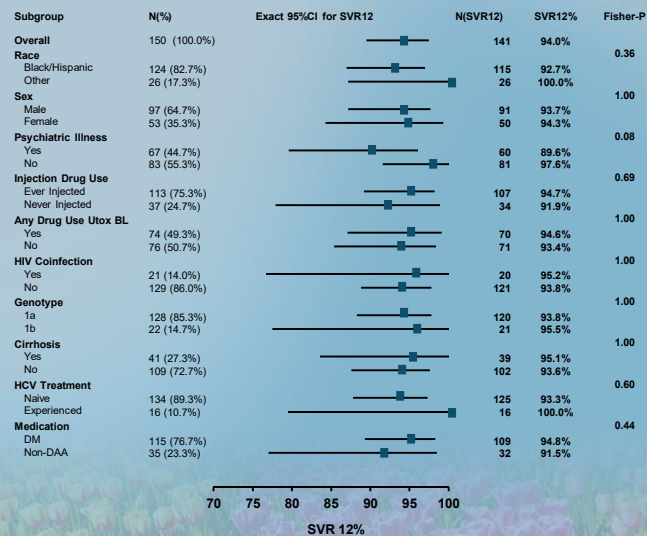


Litwin A, et al. 52nd EASL; Amsterdam, Netherlands; April 19-23, 2017. Abst. PS-130.

PREVAIL Study: SVR Results

Study Arm	ETR	SVR12
DOT	98.0% (50/51)	98.0% (50/51)
Group	93.8% (48/51)	93.8% (48/51)
Individual	96.1% (49/51)	90.2% (46/51)

Adherence Measure	10% ↑ in Adherence – OR SVR 12	P-Value
Daily Adherence	1.62 (95% CI 1.12 – 2.34)	p=0.01
Daily Window Adherence	1.82 (95% CI 1.20 – 2.75)	p=0.005



Litwin A, et al. 52nd EASL; Amsterdam, Netherlands; April 19-23, 2017. Abst. PS-130.

PREVAIL Study: Conclusions

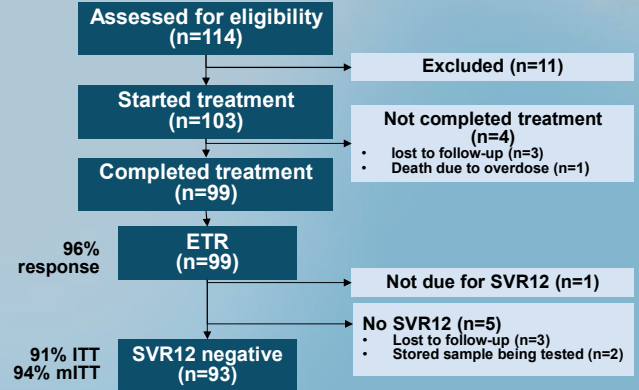
- High SVR rates achieved in persons receiving opiate agonist therapy including those actively using drugs
- Directly observed and group therapy had higher rates of adherence compared to individual care
- Similar SVR rates in all groups
- HCV treatment can be highly effective the setting of OAT

Litwin A, et al. 52nd EASL; Amsterdam, Netherlands; April 19-23, 2017. Abst. PS-130.

SIMPLIFY Study: Efficacy and Safety of SOF/VEL in People with Chronic HCV Infection and Recent Injecting Drug Use

- International study of SOF/VEL for 12 weeks in persons with recent IDU (< 6 months)
- 19 sites (Australia/New Zealand, NA, Europe)

	SOF/VEL (12 weeks) n=103
Age <40 years	25 (24)
Female sex	29 (28)
OST and injecting drug use (in last month)	
No OST, no injecting	12 (12)
No OST, injecting	33 (32)
OST, no injecting	15 (15)
OST, injecting	43 (42)
HCV genotype	
1	36 (35)
2	5 (5)
3	60 (58)
4	2 (2)
Fibrosis stage (METAVIR)	
F0-F1	59 (62)
F2-F3	27 (28)
F4	9 (9)



- No HCV relapse or re-infection to date

- SOF/VEL for 12 weeks was effective in persons with recent IDU
- Additional follow-up is needed to define risk of reinfection