Poster # 467

Real World Experience Treating HCV in Patients on Opioid Substitution Therapy in Rural Pennsylvania

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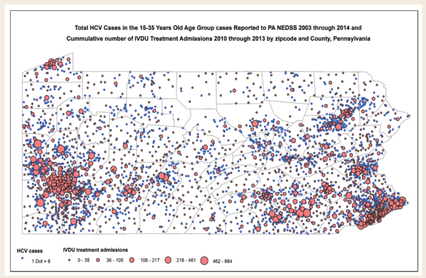
Introduction

- The newest epidemic of hepatitis C infections is occurring among younger people in rural areas in the United States.
- In Pennsylvania, the number of newly reported hepatitis C virus (HCV) infections among individuals ages 15 to 34 nearly doubled from 1,384 to 2,393 from 2003 to 2010.
- It is estimated 35-65% of individuals on opioid substitution therapy (OST) therapy are infected with HCV.
- Currently available direct acting antivirals (DAAs) can safely be used with OST and offer SVR12 rates of 92 to 97%.
- Partnerships between methadone clinics, psychiatrists and HCV treatment providers offer an opportunity to screen and link these patients into HCV care.
- We evaluated the effectiveness of linkage to HCV care in patients on OST at a rural ID clinic.

Background



- Over the past decade, a new cohort of infected 15-35 year olds has emerged and now represents the largest proportion of new cases in Pennsylvania.
- Pennsylvania has also seen an increase in opioid and other injection drug use and overdoses.
- This map demonstrates that injection drug use and young HCV cases reside in similar locations, with both urban and rural areas represented.

AASLD/IDSA Guidelines 2016

- People who inject drugs (PWID) are identified in IDSA/AASLD Guidelines as a population who should receive treatment because of the elevated risk of HCV transmission as it may yield transmission reduction benefits **(IIa, Level C)**
- PWID should be screened for risk factors for HCV and one-time testing should be performed for all persons with behaviours, exposures and conditions associated with an increased risk of HCV infection **(I, Level B)**
- Annual HCV testing is recommended for PWID and for HIV seropositive men who have unprotected sex with men. Periodic testing should be offered to other persons with ongoing risk factors for exposure to HCV **(Class IIA, Level C)**

AASLD: American Association for the Study of Liver Diseases; IDSA: Infectious Diseases Society of America; PWID: people who inject drugs;
I, Level B is conditions for which there is evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective from data derived from a single randomized trial, nonrandomized studies, or equivalent; IIa, Level C is weight of evidence and/or opinion is in favour of usefulness and efficacy from data derived from multiple randomized clinical trials, meta-analyses, or equivalent

Objective

- To compare the influence of OST therapy on SVR12 rates in HCV patients treated with DAAs.

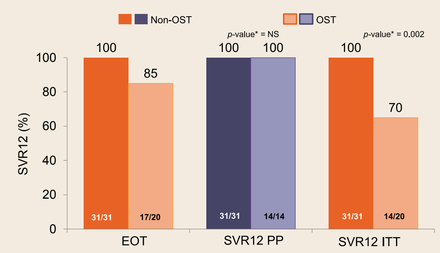
Methods

- **Setting**
  - Infectious Disease clinic in rural Pennsylvania, in the city of DuBois
  - Patients referred from local methadone clinics, psychiatrists, primary care, and self referral
- **Participants**
  - We identified 51 patients with an HCV evaluation from 1/2015 - 9/2016
- **Data Collection**
  - We reviewed medical records for patients who initiated HCV treatment
  - Patients were categorized in the OST group if they were:
    - Actively receiving opioid substitution therapy (OST) with methadone, buprenorphine, or buprenorphine/naloxone
  - OST group was compared to 31 controls not using OST
- **Data Analysis**
  - Statistical analysis using Fisher's exact test was performed to determine differences in HCV cure (SVR12) between OST and non-OST groups

Characteristic, n (%)	OST group n = 20	Non-OST Group n = 31
Median age (range)	38 (22-66)	53 (23-82)
Males	11 (55%)	21 (68%)
Race		
White	19 (95%)	29 (94%)
Depression/Anxiety	15 (75%)	14 (45%)
Genotype		
1	17 (85%)	29 (94%)
2	-	1 (3%)
3	3 (15%)	1 (3%)
Fibrosis score		
F0-F2	13 (65%)	17 (55%)
F3	2 (10%)	5 (16%)
F4	4 (20%)	5 (16%)
No data	1 (5%)	4 (13%)
Treatment naive	19 (95%)	25 (81%)
Treatment regimen		
LDV/SOF x 8 weeks	8 (40%)	9 (29%)
LDV/SOF x 12 weeks	6 (30%)	13 (43%)
Other	6 (30%)	9 (29%)

Results

SVR12 by OST



PP = Per Protocol and ITT = Intent to treat

*0.01 level of significance.

Safety

	Patients, n (%)	OST N=20	Non-OST N=31
Reasons for not achieving SVR	SVR12*	14	31
	Relapse	0	0
	Lost to Follow-Up (LTFU)	6	0
	Treatment D/C due to AE	0	0
	Death	0	0
Adverse Events (AE)	Any AE	0	0
	Treatment D/C to due AE	0	0
	Death	0	0

DAA therapy was well tolerated in both groups

* ITT analysis

Discussion

- This study showed that patients on OST who are effectively linked to care can be cured and achieved outcomes comparable to those not on OST.
  - About 1/3 of patients in the OST cohort were LTFU
  - Reasons for LTFU: transportation issues due to rural environment, failure to recognize importance of follow up, hectic lifestyle
- Cost concerns have been identified as a key barriers for lack of treatment uptake by patients with a history of substance abuse.
  - 24% of patients in the OST cohort were eligible for prescription drug assistance for DAA therapy compared to only 6% of controls
  - Recent legislation in the State of Pennsylvania passed that no longer restricts treatment to only those with advanced disease may significantly open up access to DAA therapy for this population
- Psychiatric conditions are common in this patient population and should not be a barrier to providers when initiating HCV treatment. Programs should include mental health screens with referrals.

Conclusions

- In this retrospective analysis, DAAs for 8 to 12 weeks were highly efficacious regardless of OST and psychiatric comorbidities.
- SVR12 was achieved in all patients on OST who completed follow-up.
  - SVR rates in this real world cohort were similar to those achieved in clinical trials.
- DAAs were well tolerated in patients on OST.
- Linkage of these patients can be established by collaborative networks among methadone clinics, psychiatrists, and HCV specialists.
- Addressing drug addiction in rural America along with increasing HCV treatment uptake will be vital to the elimination of HCV.

Implications

- Co-locating HCV treatment and substance abuse treatment services in the same clinical environment will significantly improve HCV treatment uptake and compliance.
  - A "mobile" approach would eliminate the transportation issues that plague rural Pennsylvania.
- Patients on OST and psychiatric comorbidities may benefit from a patient navigator to ensure follow-up.

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Disclosures

- Tuesdae Stainbrook: Gilead and BMS advisory board and speakers bureau.
- Sarjita Naik: Employee of Gilead Sciences.