Poster #660

Identifying and Prioritizing Hepatitis C Treatment for HIV-Hepatitis C Co-Infection

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THE DC COHORT, Advancing HIV Care and Treatment in the District of Columbia

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BACKGROUND

- In Washington, DC an estimated 9% of HIV-infected persons have a diagnosis of chronic Hepatitis C infection (HCV).
- HCV management guidelines recommend:
  - Most patients receive treatment unless they have limited life expectancy due to a co-morbidity; and
  - Prioritization of treatment based on host factors including co-infections and degree of liver fibrosis.
- Drug cost for directly acting agents is substantial ($84-100K/patient) and the number of experienced U.S. healthcare providers is insufficient to treat all patients immediately.

OBJECTIVES

- To describe the prevalence and incidence of HCV, and risk factors for disease progression and transmission in incident HCV cases among a large urban cohort of HIV+ patients.

METHODS

DC COHORT

- A longitudinal observational cohort study of HIV-infected persons in care in Washington, DC at 13 participating clinical sites.
- Data abstracted from participants' electronic medical records manually and through electronic exports.
- Included participants enrolled 1/2011 -12/2014 with an HCV diagnosis either at baseline or during the follow-up period.

ANALYSIS

- Categorized patients into treatment categories according to the IDSA/AASLD HCV treatment guidelines.
- Conducted descriptive analysis to identify differences among HIV only and HIV-HCV patients.

RESULTS

Table 1. Characteristics of DC Cohort Participants by HCV Status (N=6,479)

Characteristics	HIV mono-infection		Prevalent HIV/chronic HCV co-infection[1]		Incident HCV diagnoses[2]		P-value[3]
Total in analytic cohort	**5,614**		**865**		**198**		
	median (IQR)		**median (IQR)**		**median (IQR)**		
Person months of follow-up since consent	30.7 (16.6, 39.9)		34.2 (17.0, 41.0)		39.4 (27.0, 42.9)		**<0.001**
Age (years)	45.2 (35.0, 52.8)		55.9 (50.8, 59.9)		52.6 (46.2, 58.9)		**<0.001**
Years HIV positive	8.9 (4.0, 15.9)		14.0 (6.9, 20.2)		13.6 (7.5, 20.4)		**<0.001**
	N	**%**	**N**	**%**	**N**	**%**	
Sex							**0.0469**
Male	4,070	72.5	655	75.7	159	80.3	
Race/ethnicity							**<0.001**
Non-Hispanic black	4,219	75.2	753	87.1	150	75.8	
Non-Hispanic white	821	14.6	77	8.9	30	15.2	
Hispanic	257	4.6	13	1.5	7	3.5	
Other	115	2.0	10	1.2	1	0.5	
Unknown	202	3.6	12	1.4	10	5.1	
HIV transmission risk							**<0.001**
MSM	2,281	40.6	138	16.0	71	35.9	
High risk heterosexual	1,721	30.7	190	22.0	49	24.7	
IDU	142	2.5	302	34.9	37	18.7	
MSM and IDU	55	1.0	24	2.8	7	3.5	
Other/Unknown	1,415	25.2	211	24.4	34	17.2	
Housing status							**0.0543**
Permanent/stable	4,550	81.0	669	77.3	151	76.3	
Temporary/unstable	408	7.3	70	8.1	16	8.1	
Homeless	122	2.2	30	3.5	7	3.5	
Other	37	0.7	7	0.8	1	0.5	
Unknown	497	8.9	89	10.3	23	11.6	
Employment status							**<0.001**
Employed	1,773	31.6	199	23.0	54	27.3	
Unemployed	1,591	28.3	406	46.9	60	30.3	
Retired	152	2.7	37	4.3	2	1.0	
Student	149	2.7	2	0.2	0	0.0	
Disabled	18	0.3	7	0.8	0	0.0	
Other	134	2.4	5	0.6	5	2.5	
Unknown	1,797	32.0	209	24.2	77	38.9	
Insurance status							**<0.001**
Private	1,650	29.4	121	14.0	48	24.2	
Public	3,638	64.8	709	82.0	138	69.7	
Other	146	2.6	15	1.7	2	1.0	
Unknown	180	3.2	20	2.3	10	5.1	
Co-morbid conditions							
Mental health	1,904	33.9	427	49.4	84	42.4	**<0.001**
Substance abuse	638	11.4	110	12.7	26	13.1	0.2466
Alcohol abuse	749	13.3	119	13.8	26	13.1	0.7384
HIV Viral load (copies/ml)[4,5]							0.1955
0-199	4,012	71.5	659	76.2	145	73.2	
200-299	104	1.9	13	1.5	1	0.5	
300-399	70	1.2	4	0.5	3	1.5	
400-999	167	3.0	28	3.2	4	2.0	
1,000-9,999	354	6.3	41	4.7	9	4.5	
10,000-49,999	338	6.0	31	3.6	5	2.5	
50,000-99,999	140	2.5	21	2.4	3	1.5	
≥100,000	230	4.1	29	3.4	6	3.0	
Unknown	199	3.5	39	4.5	22	11.1	
Median (IQR)	20 (10, 230)		20 (10, 84)		20 (10, 66)		0.8559
Site of care							0.8101
Community based clinic	2,757	49.1	421	48.7	117	59.1	
Hospital based clinic	2,857	50.9	444	51.3	81	40.9	

[1] Defined as co-infected with HCV if had ICD9 diagnosis code indicating chronic or unspecified HCV or a positive HCV Ab or viral load lab test ≤7 days post consent date.
[2] Participants were considered to have an incident diagnosis of HCV if they had an ICD9 diagnosis code indicating chronic or unspecified HCV or a positive HCV Ab or viral load lab test dated >7 days after consent date and had no prior indication of HCV.
[3] P-values are comparing HIV mono and HIV/HCV co-infected participants at baseline. P-values for categorical variables were obtained from chi-square tests or Cochran-Armitage tests for trend; p-values for continuous variables were obtained from Wilcoxon rank sum tests.
[4] Closest value within six months prior to consent and one month after consent. Undetectable viral loads were assigned a value of one-half the lower limit of detection.
[5] For incident HCV diagnoses, closest value within six months prior to HCV diagnosis and one month after HCV diagnosis. Undetectable viral loads were assigned a value of one-half the lower limit of detection.

Figure 1. HCV RNA Distribution among Persons with Incident HCV Infection (N=54)

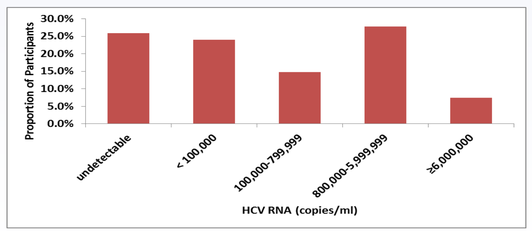

Figure 2. Treatment Regimens for Participants with Incident HIV/HCV Co-Infection (N=14)

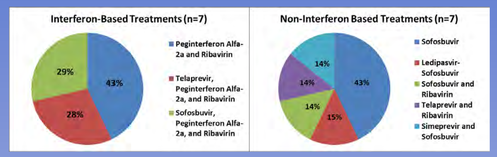

Table 2. Categorization of Untreated HCV among DC Cohort Participants (N=293)

IDSA/AASLD Treatment Category	N (%)
Highest Priority	
Advanced fibrosis or compensated cirrhosis (F3,F4) (defined by APRI (>1.0) or FIB4 scores (>3.25))	65 (22.2)
Organ transplant[1]	0 (0.0)
Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis)	2 (0.7)
Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis	9 (3.1)
Pts who meet any of the above criteria	**71 (24.2)**
High Priority	
Fibrosis (APRI 0.5-1.0 or FIB4 1.45-3.25)(F2)	138 (47.1)
Hepatitis B virus coinfection	17 (5.8)
Other coexistent liver disease (eg, [NASH])	1 (0.3)
Debilitating fatigue	25 (8.5)
Type 2 diabetes mellitus (insulin resistant)	44 (15.0)
Porphyria cutanea tarda	0 (0.0)
Pts meeting any of the above criteria not already in the highest risk group	**136 (46.4)**
Elevated Risk of HCV transmission	
Men who have sex with men (MSM) with high-risk sexual practices	92 (68.6)
Active injection drug users	87 (29.7)
Incarcerated persons[1]	0 (0.0)
Persons on long-term hemodialysis[1]	0 (0.0)
HCV-infected women of child-bearing potential wishing to get pregnant[1]	0 (0.0)
Pts who meet any of the above criteria and not already in the highest or high-risk groups	**47 (16.0)**
Untreated pts not in any of the above three groups, i.e. low risk group	**39 (13.3)**

[1] Information is not collected in the DC Cohort regarding organ transplants, incarcerations, long-term hemodialysis, or intended pregnancies thus these items could not be measured.

RESULTS

- 865 (13.3%) participants had a diagnosis of chronic HCV at the time of enrollment in the DC Cohort. (Table 1)
- 198 (3.5%) participants had a new diagnosis of HCV co-infection; a rate of 1.56 infections per 100-person years. (Table 1)
- Among incident HCV infections, most were male, black, MSM, publically insured, HIV virally suppressed, and receiving care at a community-based clinic. (Table 1)
- 35% of participants had HCV RNA levels over 800,000 copies/ml. (Figure 1)

RESULTS (CONT'D)

- Few participants (n=14; 7.1%) with incident HCV infections were treated for their HCV. (Figure 2)
- Median APRI score was 0.4 (IQR 0.3, 0.8); median FIB4 score was 1.7 (IQR 1.1, 2.8).
- In addition to their HIV, 71% of co-infected participants met IDSA/AASLD priority treatment criteria with an additional 16% meeting treatment criteria due to elevated transmission risk. (Table 2)

CONCLUSIONS

SUMMARY

- HIV/HCV co-infection is relatively common with a remarkably high rate of incident infections.
- The majority of new infections are receiving HIV care at community based clinics.
- Most HIV/HCV co-infected patients have factors placing them at highest priority for treatment according to the current guidelines.

LIMITATIONS AND STRENGTHS

- Limitations include missing HCV RNA levels, lack of HCV genotype data, and use of ICD9 and serologic estimates of fibrosis to characterize risk.
- Strengths include the large, representative sample of the DC Cohort.

DISCUSSION

- With few participants previously treated for their HCV infection, providing prompt therapy will require substantial financial and workforce resources.
- Estimated treatment costs for this cohort are $28-54 million, which if extrapolated to all HIV/HCV infected persons in DC will cost an estimated $134-261 million.
- HIV care providers should regularly screen for HCV infection, identify persons at high priority for treatment, and ensure treatment access to those in need.

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