

HCV Treatment Initiation Among HCV Infected PWID in CAPICA, A Retrospective Study in Twelve Canadian Clinical Settings

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Study Rationale & Design

CAPICA: Characterization of HCV Infected people who inject drugs (PWID) in the Setting of Clinical Care in Canada

The CAPICA study is a multicenter, retrospective, database/chart review conducted in 12 centers in Canada.

The overall objectives of CAPICA were :

- To describe HCV disease in PWID who are engaged in care for their HCV infection in a clinical setting in Canada.
- To define the demographics and health determinants, characteristics of injection drug use, opiate substitution therapy, HCV disease characteristics and HCV treatment history in these patients.

423 subjects receiving medical care, with chronic HCV infection, and a history of injection drug use within twelve months were included. Data was collected from October 2015 to February 2016.

Number of sites per province:



Inclusion Criteria:

- Male or female patients ≥ 18 years of age
- Patients who have a documented diagnosis date of HCV and an HCV RNA test result in their chart and are chronically infected with HCV at the time of enrollment
- Patients who have documented use of injection drugs and contact with the clinic within the last 12 months

Exclusion Criteria:

- Patients who are co-infected with HIV

Characteristics of the study sample:

This is a cross-sectional study representing a specific patient population in a defined time frame. Only patients with current chronic HCV infections were enrolled. Patients with ongoing treatments could be included. Thus, patients previously treated who achieved SVR were excluded.

Analysis: Socio-demographic, HCV-related and behavior characteristics were summarized using frequency and percentages. Logistic regression was conducted to examine factors associated with HCV treatment status.

Limitations

- This study represents a snapshot of patients followed in these clinics who were actively using injection drugs and were HCV infected during the period chosen for data collection.
- The sample may over-represent patients with personal or systemic barriers to HCV treatment, as patients treated prior to the study period were systematically excluded.
- As for many retrospective studies using clinical data, missing data may have affected results.
- Nevertheless, this study gathered important information on characteristics of PWIDs currently accessing health care and HCV treatment in the new era of DAA treatments.

Objectives of this investigation

- To describe patients characteristics in relation to HCV treatment status among PWIDs recruited in CAPICA
- To examine HCV treatment status and its association with liver disease and drug and alcohol related behaviors among PWID recruited in CAPICA

Results

Table 1. Patient Characteristics

Variables	All patients n=423*	Not Treated n=352	All-Oral DAA n= 30	PR or DAA+PR n=39
Sociodemographic Characteristics				
Median age, y (range)	42.0 (18.0-69.0)	41.0 (18.0-67.0)	51.0 (23.0-69.0)	46.0 (24.0-64.0)
Male, n (%)	314 (74.2%)	255 (72.4%)	26 (86.7%)	31 (79.5%)
Caucasian, n (%)	274 (64.8%)	219 (62.2%)	19 (63.3%)	35 (89.7%)
Aboriginal, n (%)	50 (11.8%)	44 (12.5%)	6 (20.0%)	0 (0.0%)
Housing Status				
Homeless/in shelters	105 (24.8%)	92 (26.1%)	3 (10.0%)	10 (29.4%)
Literacy Level				
< High School	109 (25.8%)	87 (24.7%)	8 (26.7%)	13 (33.3%)
≥ High School	79 (18.7%)	65 (18.5%)	6 (20.0%)	8 (20.5%)
Unknown / Not Available	235 (55.6%)	200 (56.8%)	16 (53.3%)	18 (46.2%)
HCV Disease Characteristics				
HCV Genotype				
GT1a	199 (47.0%)	159 (45.2%)	17 (56.7%)	22 (56.4%)
GT3	122 (28.8%)	101 (28.7%)	10 (33.3%)	11 (28.2%)
Other or Unknown	102 (24.1%)	92 (26.1%)	3 (10.0%)	6 (15.4%)
Fibrosis – Most Recent Metavir Score				
F0/F1	151 (35.7%)	141 (40.1%)	2 (6.7%)	7 (17.9%)
F2	59 (13.9%)	39 (11.1%)	8 (26.7%)	12 (30.8%)
F3	27 (6.4%)	16 (4.5%)	8 (26.7%)	3 (7.7%)
F4	38 (9.0%)	18 (5.1%)	11 (36.7%)	8 (20.5%)
Unknown	148 (35.0%)	138 (39.2%)	1 (3.3%)	9 (23.1%)
Drug Use Characteristics				
Frequency of injections				
Daily	141 (33.3%)	128 (36.4%)	5 (16.7%)	8 (20.5%)
Weekly	83 (19.6%)	64 (18.2%)	10 (33.3%)	8 (20.5%)
Monthly	49 (11.6%)	41 (11.6%)	2 (6.7%)	5 (12.8%)
Other / Unknown	150 (35.5%)	119 (33.8%)	13 (43.3%)	18 (46.2%)
Injection Drug Use				
Prescription Opioids	218 (51.5%)	185 (52.6%)	14 (46.7%)	18 (46.2%)
Cocaine	172 (40.7%)	139 (39.5%)	10 (33.3%)	23 (59.0%)
Heroin	146 (34.5%)	131 (37.2%)	3 (10.0%)	10 (25.6%)
Methamphetamine	97 (22.9%)	85 (24.1%)	7 (23.3%)	5 (12.8%)
Other	23 (5.4%)	19 (5.4%)	2 (6.7%)	2 (5.1%)
Unknown	12 (2.8%)	8 (2.3%)	3 (10.0%)	1 (2.6%)
Alcohol Consumption per Week**				
None	122 (28.8%)	102 (29.0%)	6 (20.0%)	14 (35.9%)
Low-risk drinking	105 (24.8%)	71 (20.2%)	14 (46.7%)	18 (46.2%)
High-risk drinking	65 (15.4%)	55 (15.6%)	7 (23.3%)	3 (7.7%)
Unknown	131 (31.0%)	124 (35.2%)	3 (10.0%)	4 (10.3%)

- * 2 patients for which treatment regimen was unknown are not included in the table
- ** **Low risk drinking** was defined as up to 10 drinks for female and up to 15 drinks for men, per week, as defined in reference 1.

Figure 1. HCV Genotype

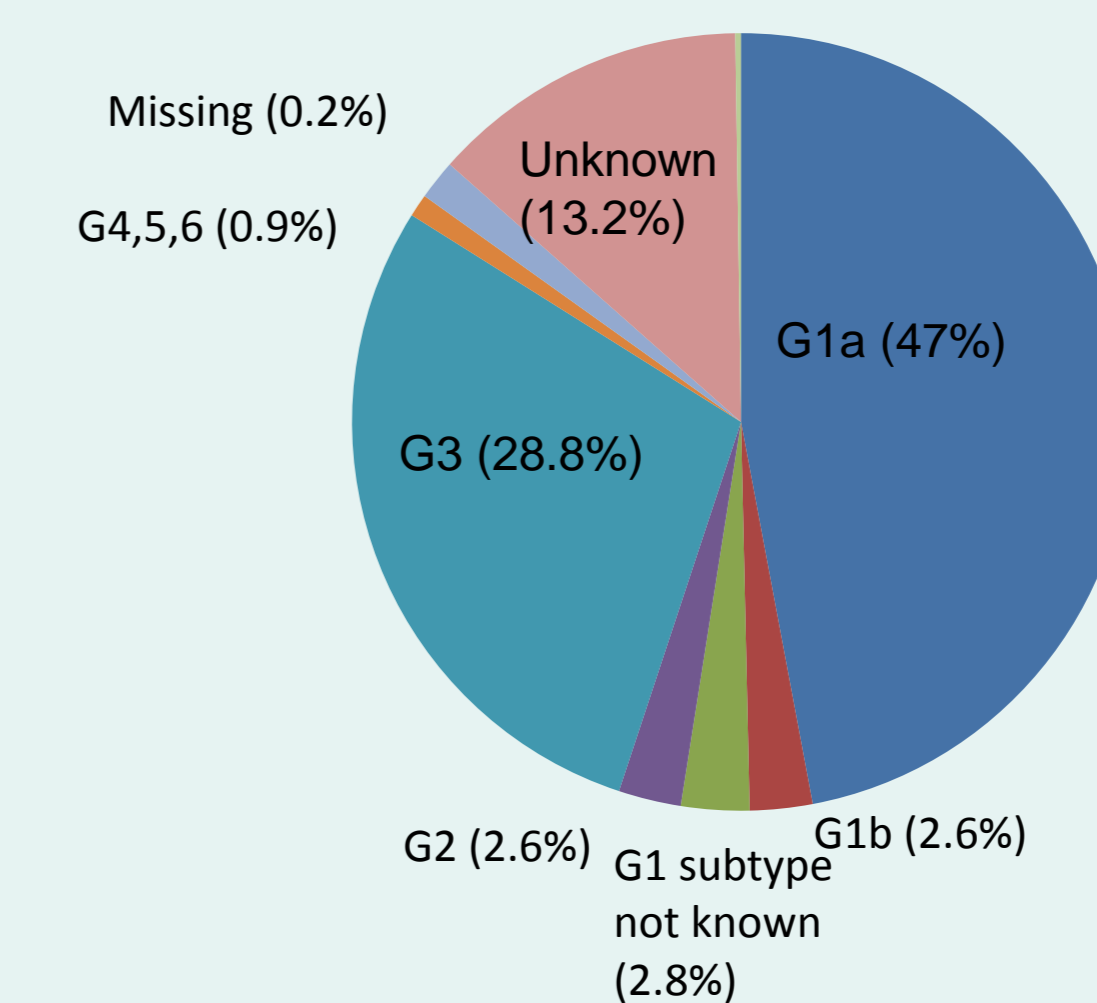
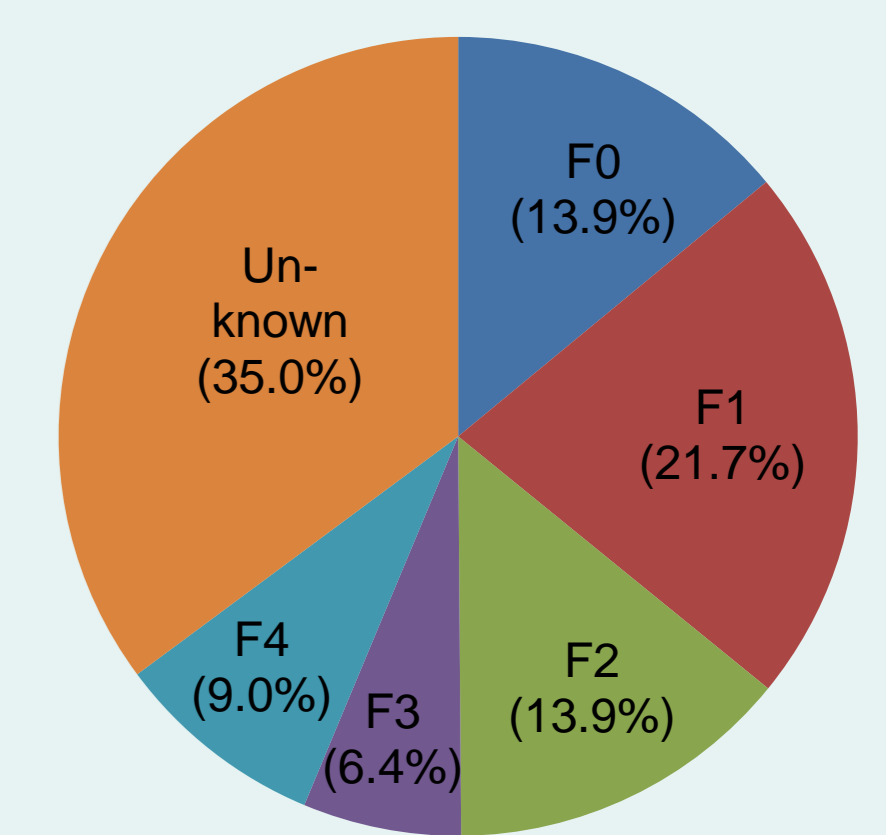


Figure 2. Fibrosis Score



- No difference was observed in the demographic characteristics between PWIDs who received all-oral DAAs vs. PegIFN containing regimens. Therefore, all HCV treatments were merged into one category in the multivariate analysis.
- Of all drugs injected, only heroin injection was negatively associated with HCV treatment in univariate analyses. The variable was, however, not retained in the multivariate model.

Table 2. Multivariate Analysis - Factors associated with HCV treatment – analysis by logistic regression

Factors	Adjusted Odds Ratio	95% CI
Increasing Age (per year increment)	1.05	1.02 – 1.08
Female gender	1	1
Male gender	1.23	0.58 – 2.63
Fibrosis Score: F0-F3 (ref)		
F4	4.90	2.12 – 11.31
Unknown Fibrosis Score	0.50	0.23 – 1.11
Genotype other than 1		
Genotype 1	1.39	0.74 – 2.61
Unknown Genotype	0.25	0.05 – 1.22
High risk alcohol drinking		
Low-risk alcohol drinking	3.59	1.45 – 8.87
No alcohol use	1.08	0.42 – 2.77
Unknown alcohol use	0.35	0.11 – 1.06
Daily drug injection		
Not daily	1.98	0.90 – 4.30
Unknown drug injection frequency	2.86	1.24 – 6.58

Conclusions

- Overall, 17% of PWIDs followed in the participating centers received HCV treatment. Among HCV patients with advanced liver fibrosis (F3 or F4), 46% have been exposed to HCV treatment.
- Conversely, only 10 out of 151 (7%) patients with F0/F1 have received HCV treatment. Older age, and having a cirrhosis were independently associated with treatment status, suggesting that HCV treatment was prioritized on the basis of HCV disease severity at the time of the study. In addition, because of funding limitations, F0/F1 patients have practically no access to new DAA therapies.
- Consistent with previous studies², Our findings suggest that daily and/or high-risk alcohol and drug use patterns remain barriers to HCV treatment in multidisciplinary settings.
- Low-risk alcohol use was positively associated with treatment. It is plausible that patients engaged in HCV care modified their alcohol use patterns prior to HCV treatment, as part as a shared decision making process fostered in multidisciplinary settings. Alternatively, low-risk drinking in this population can be a marker of good social functioning.
- This study is allowing for improved characterization of HCV infection in PWID currently engaged in care in Canada. This study also highlights the feasibility and potential to reach and treat a significant number of PWIDs infected with HCV at earlier stage, before the occurrence of liver complications.

Reference: 1. Butt, P., D. Beirness, L. Gliksmann, C. Paradis, et T. Stockwell (2011). Alcohol and health in Canada: A summary of evidence and guidelines for low-risk drinking, Ottawa (ON), Canadian Centre on Substance Abuse.
2. Treloar C, Hull P, Dore GJ, Grebely J. Knowledge and barriers associated with assessment and treatment for hepatitis C virus infection among people who inject drugs. Drug Alcohol Rev. 2012;31:918–24.
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