Clinical and virological characteristics of HIV and HCV co-infected versus HCV monoinfected patients: a real-life evaluation in the PITER

(Piattaforma Italiana per lo studio della Terapia delle Epatiti viRali) cohort

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INTRODUCTION

Due to shared routes of transmission, HIV co-infection is common among patients with chronic HCV infection. On the other hand, in Italy more than 22,000 HIV infected patients in care, also carry HCV infection, and more than 7,000 of them have advanced liver disease. HIV co-infection increases the rate of chronicity and accelerates progression of HCV-related liver disease.

PITER (Piattaforma Italiana per lo studio della Terapia delle epatiti ViRali) is a multicentric cohort study, developed as a collaboration among the Istituto Superiore di Sanita', the Italian Society for the Study of the Liver (AISF) and the Italian Society for Infectious Diseases (SIMIT). It aims to address the epidemiological burden of HCV and HIV co-infected patients in care with the final goal to address challenges in the field of therapy of HCV, as well as the long term effect of SVR in the natural history of HCV and HIV co-infections

AIM

In this cross sectional analysis we aimed to characterize the HIV/HCV co-infected patients enrolled in PITER-HCV cohort according to socio-demographic, clinical and virological profiles and in relation to the treatment prioritization algorithm.

MATERIALS AND METHODS

The cohort of 8500 patients consecutively enrolled by more than 80 Italian clinical centers over the last 12 months within the PITER framework is a representative sample of HCV chronic infected patients in care. The web-based platform contains detailed clinical data of the enrolled patients. For this study the analysis included 7359 patients. Descriptive analysis is performed for the baseline parameters.

RESULTS

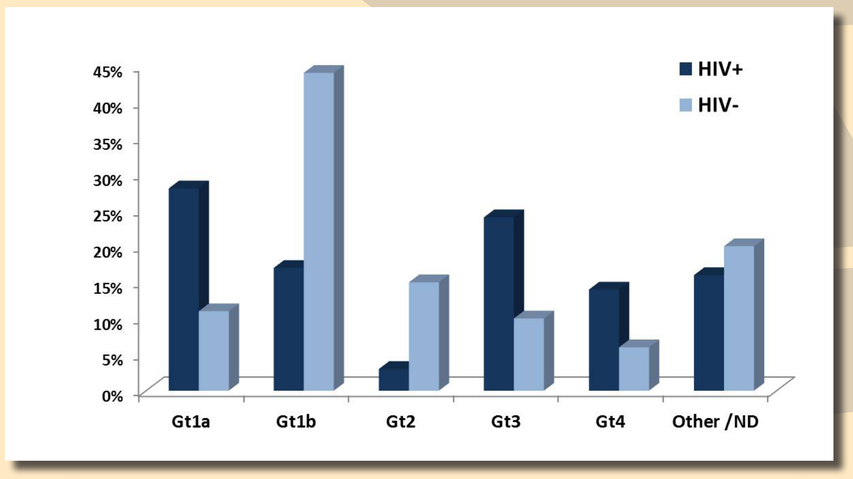
A HIV infection is present in 6.5 % of patients with HCV chronic infection consecutively enrolled in PITER (448/7359) and 73% of them are men.

Antiretroviral therapy in HIV/HCV co-infected patients

Anti-HIV treatment	% of HIV/HCV co-infected patients
PI-based regimens	54%
INSTI-based regimens	42%
NNRTI-based regiments	19%
Treatment intensification with *CCR5 antagonist*	0.4%

B HIV/HCV co-infected patients are significantly younger than HCV mono-infected patients: median age is 51 years (SD 6 years) *vs* 61 years (SD 12 years) respectively ($p<0.05$).

C HIV/HCV co-infected patients have a different distribution of HCV genotypes.



HCV genotype distribution in HIV/HCV co-infected *vs* mono-infected patients

D Clinical cirrhosis is present in 31% of HIV/HCV co-infected patients *vs* 39% of HCV mono-infected patients.

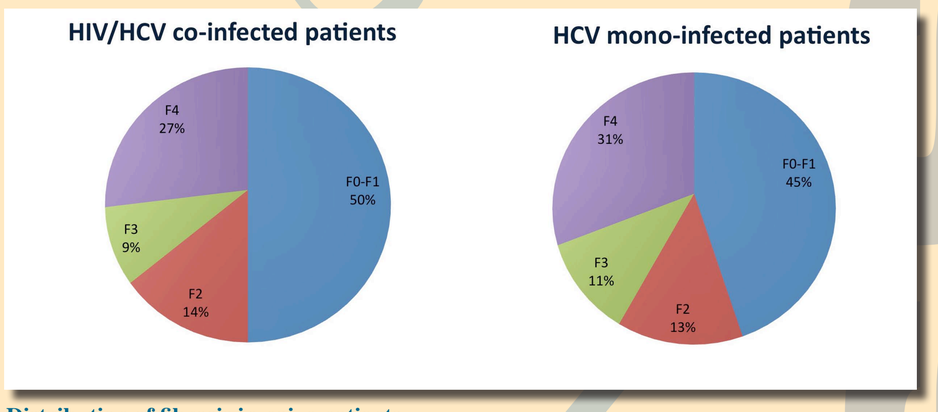
E Fibrosis stage distribution is similar in HIV/HCV co-infected *vs* HCV mono-infected patients.

	HIV-HCV coinfected	HCV monoinfected
F0-F1	28%	22%
F2	10%	8%
F3	7%	7%
F4/cirrhosis	31%	38%
Missing	24%	25%

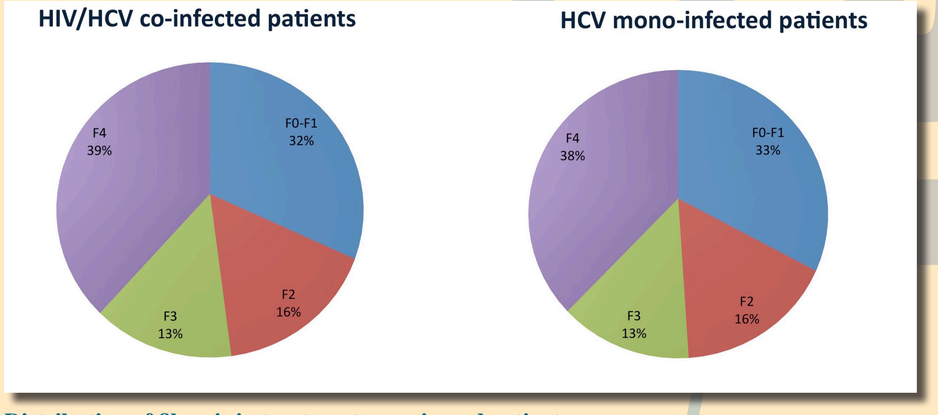
Notably, the fibrosis stage is comparable in HIV/HCV co-infected *vs* HCV mono-infected patients despite the significant differences ($P<0.01$) in median age (51±6 VS 61±12 years, respectively)

The clinical profile of liver disease is reported in terms of fibrosis stage defined according to the fibroscan data (available in 68% of patients).

F In both naïve and treatment experienced patients, a similar distribution of fibrosis stage is observed in HIV/HCV co-infected patients and HCV mono-infected patients.



Distribution of fibrosis in naive patients

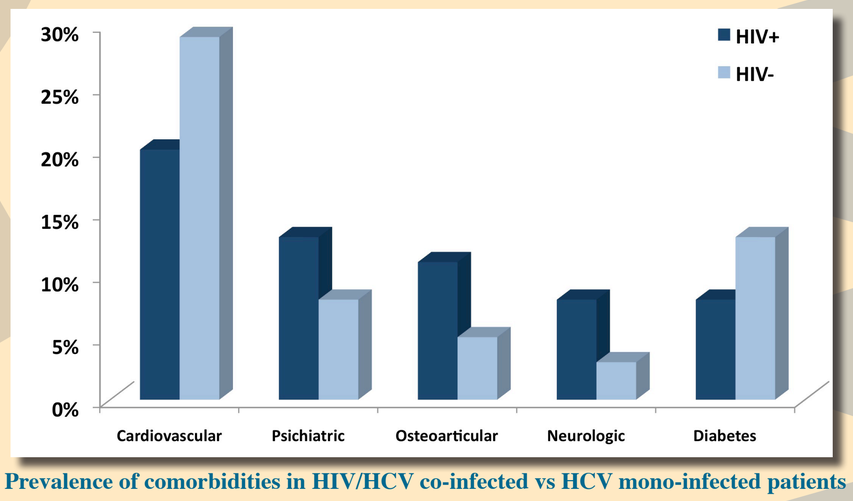


Distribution of fibrosis in treatment experienced patients

The percentages are calculated considering patients tested for HIV infection. Similar results were obtained considering the patients for whom HIV infection was not tested.

G 33% of HIV/HCV co-infected patients were previously treated with IFN-based therapy compared to 53% of HCV mono-infected patients.

H In HIV/HCV co-infected patients and HCV mono-infected patients, the prevalence of specific comorbidities were: cardiovascular diseases 20% *vs* 29%; psychiatric diseases 13% *vs* 8%; osteoarticular diseases 11% *vs* 5%; neurologic diseases 8% *vs* 3%; diabetes 8% *vs* 13% respectively.



Prevalence of comorbidities in HIV/HCV co-infected vs HCV mono-infected patients

CONCLUSIONS

- The high cost of DAA has generated allocation policies mostly based on fibrosis staging as a surrogate for immediate treatment needs.
- The EASL 2015 Guidelines considers HIV co-infection as an HCV treatment priority because it increases the rate of chronicity and accelerates the progression of liver disease. The prioritization algorithm endorsed by AIFA is mostly based on fibrosis and to date allows reimbursement of DAA in Italy only for about 30-38% of the HCV/HIV co-infected patients.
- Allocation of DAA according to the priority rules should consider access to therapy in all co-infected patients independently of fibrosis stage. The impact of anti-HCV treatment in relation to differences in sociodemografic, virological, and comorbidity pattern in HIV coinfected patients should be evaluated.

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