**Characteristics of HIV/HCV co-infected individuals seen for care in Italy: a description using data from ICONA and HepaICONA cohorts**

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**Abstract:**

**Background:** The availability of oral antivirals has completely changed the therapeutic approaches to anti-HCV therapy increasing the rate of success and tolerability. However, the high cost of these drugs is a big challenge for National Health Institutions and accurate estimates of the number of patients with the highest priority for treatment and of those with the highest rate of response to treatment are required. Priority for treatment is based on stage of liver fibrosis (people with more advanced disease should be treated first) and treatment success is related to the HCV infecting genotype, stage of liver disease and the history of previous failure of Pegylated Interferon (PegIFN) based therapies. Thus, the knowledge of the prevalence of these characteristics among persons living with HIV and HCV (PLHIV-HCV) is crucial to estimate oral antivirals treatment uptake over the next few years.

**Aim:** To estimate the proportion of patients with advanced fibrosis with or without liver decompensation who had a history of treatment with PegIFN according to HCV genotype in PLHIV-HCV seen for care in Italy.

**Methods:** A cross-sectional descriptive analysis of PLHIV-HCV enrolled in the ICONA and HepaICONA Foundation Study cohorts at the time of their most recent clinical visit (if after 1 January 2010). Stage of liver disease was estimated using the Fib-4 score (METAVIR cut-offs) with or without decompensation and their previous history of anti-HCV treatment stratified according to HCV genotype.

**Results:** We identified 1,462 PLHIV-HCV on average of 50 years of age [IQR 46-53], 380(26%) female, IVDU 1,060 (73%). Median calendar year of last clinical visit 2014 [IQR 2010-2015]. Distribution of HCV genotypes (G) was: G1a, 439(30%); G1b, 178(12%); G2, 35(2%); G3a, 339 (23%); G4, 147(10%). 92% were currently receiving ART. Of these, PI/r used were: LPV/r (8%), ATV/r (22%), DRV/r (16%); most frequently used NRTI pair was TDF+FTC (48%) and EFV (15%) in the NNRTI class. Median [IQR] biomarkers values were: Hb g/dL 15[IQR 13-16], neutrophils 10⁷/uL 3,129[IQR 2,300-4,210]; PLT 10⁷/uL 181[137-226], ALT 10⁵/IU 48[31-79]. Most common co-morbidity was psychiatric disorders 289(20%); current alcohol use was reported by 281(19%). Advanced fibrosis (Fib-4 score >3.45) was observed in 216(15%, 95%CI:13-17); 35(2%, 95%CI:1-3) had a clinical diagnosis of hepatic decompensation; 388(27%, 95% CI:24-29) had moderate fibrosis (Fib-4 score 1.45-3.45) and 484(33% 95 CI: 31-36) mild fibrosis (Fib-4 score <1.45); Fib-4 score unknown in 374(26%). 321(22%, 95%CI: 20-24) previously received therapy with PegIFN: 131(17%) G1 or G4, 5(14%) G2 and 60(18%) G3.

**Conclusion:** Close to the time of first introduction of DAA into clinical care, up to 17% of PLHIVHCV satisfied the criterion of highest priority for anti-HCV treatment and up to 29% a moderate priority due to their disease stage. Less than one fourth of the studied population had previously used PegIFN.