Feasibility of Pegylated Interferon (PegIFN) based therapies in HIV/HCV co-infected individuals seen for care in Italy: an estimate using data from ICONA and HepaICONA cohorts

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Abstract:

Background: Pegylated interferon (PegIFN)-based therapies with or without Sofosbuvir/Simeprevir is the only option available in Italy for HIV/HCV-infected patients without advanced liver fibrosis. This is also the treatment option recommended by European AIDS Clinical Society guidelines for PegIFN-naïve patients without liver cirrhosis. However, access to this treatment could be challenged in co-infected people because of patients’ refusal and major contraindications. In addition, minor contraindications require supportive measures which can increase costs and complexity of PegIFN-based treatment (i.e. transfusions, growth factors, antidepressants, etc.)

Aim: To estimate the proportion of patients with minor and major contraindications to PegIFN-based therapies in HIV/HCV co-infected PegIFN-naïve patients without advanced liver disease and enrolled in two large cohorts in Italy.

Methods: A cross-sectional descriptive analysis of HIV/HCV co-infected patients enrolled in ICONA and HepaICONA cohorts at the time of their most recent clinical visit (if after 1 January 2010). We considered only PegIFN-naïve and identified major contraindications to PegIFN according to Summary of Product Characteristics. We also identified minor contraindications such as: anemia, neutropenia, thrombocytopenia, psychiatric disorders, diabetes, hypertension and current alcohol use. We did not take into account drug-drug interactions (DDIs) between Simeprevir and cART in this analysis because this drug could be replaced by Sofosbuvir in PegIFN-based therapies for HCV genotype (G) 1 and G4.

Results: We identified 1,462 patients with HIV/HCV of median age 50y [IQR 46-53], 380(26%) females, IDU 1060 (73%). Median calendar year of last clinical visit was 2014 [IQR 2010-2015]. Distribution of genotype: G1a, 439 (30%); G1b, 178(12%); G2, 35(2%); G3a, 339(23%); G4, 147 (10%). Fib-4 score data were not available in 374 (26%), 216(15%, 95%CI: 12.9-16.7) showed advanced (Fib-4 score >3.45) liver fibrosis and 193(13%) previously received PegIFN. The percentage of PegIFN-naïve patients without advanced fibrosis (Fib-4 score ≤3.45) and without major contraindications was 95% in G1 or G4, 76% in G2, and 66% in G3. However, in these patients without major contraindications, ≥1 minor contraindication was present in 50% with G1 or G4, 41% with G2 and 48% with G3. Therefore, overall only, 252 patients (170/363 with G1 or G4, 13/23 G2 and 69/133 G3) out of 679 (37%, 95% CI: 33.4-40.8) were PegIFN-naïve people without advanced fibrosis and with no major or minor contraindications to PegIFN-based therapies.

Conclusion: Although most of the potential HIV/HCV co-infected candidates for PegIFN-based treatment did not show major contraindications to PegIFN, only 37% of our patients were free of minor contraindications, thus most of them will probably require additional support that may decrease the cost effectiveness of PegIFN-based therapies.