Oral Poster **Session/Topic:** **Immuno-virological determinants**

N. **Title:**

OP 7 **Direct acting anti-viral (DAA) therapeutic options 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: Directly active antivirals (DAA) for HCV and anti-HIV treatment share several metabolic pathways and drug-drug interactions (DDI) are a major challenge in persons living with HIV (PLHIV). The proportion of PLHIV with HCV who will be able to benefit from DAA without modifying their cART remains unknown.
Aim: To estimate the number of anti-HCV treatment options with DAA without potential clinically significant DDI with ongoing cART in PLHIV with HCV patients enrolled in two large cohorts in Italy.
Methods: In a cross-sectional descriptive analysis of PLHIV with HCV enrolled in ICONA and HepaICONA cohorts at the time of their most recent clinical visit (if after 1 January 2010) we identified all patients receiving a cART regimen and showing significant DDI with DAA which should be used alone and/or with Sofosbuvir.
Results: We included 1,462 PLHIV with HCV of median age 50 years [IQR 46-53], 380(26%) female. Median calendar year of last clinical visit 2014 [IQR: 2010-2015]. Distribution of genotypes (G) was: G1a 439 (30%); G1b 178 (12%); G2 35(2%); G3a 339(23%); G4 147(10%); 216(15%, 95%CI: 12.9-16.7) showed advanced liver fibrosis and 92% were on ART. Out of 764 patients with G1 or G4, 16 showed Child B liver function which is a contraindication for anti-HCV NS3/NS4 inhibitors; 503 (67%) out of 748 compensated patients were receiving cART not compatible with the use of Simeprevir :356 (47%) were treated with PI/r and 170 (22%) with EFV, NVP or ETV. 385/748 (51%) were receiving cART with clinically significant interactions with 3D: 118(16%) DRV/r BID, 61 (8%) other PI/r except DRV/r QD or ATZ/r and 206(27%) were using NNRTI. 180 (24%) with G1 or G4 and 91(26.8%) with G3 were using TDF+PI/r which should be used with caution with Ledipasvir. Overall, regardless of genotype, 10% (95%CI: 8.5-11.6) already appeared to have lost all DAA options except Daclatasvir and this estimate was 15% (95%CI: 10.4-20.3) in patients with advanced fibrosis. Out of 588 patients with G1, G3 or G4, 306(52%) were receiving ATZ/r or EFV or NVP or FPV/r or SQV/r which should be used with adjusted doses of Daclatasvir. Ribavirin (RBV) was absolutely contraindicated in 11 (2%) with hemoglobin(Hb) <10 g/dL, while anemia (Hb <13 g in males or <12g in females) that is a minor contraindication to RBV was present in 179(32%) with similar prevalence across all genotypes.
Conclusion: Daclatasvir in combination with Sofosbuvir could be administered to all PLHIV with HCV and for 10% of our study population was the only option without significant DDI (however, Daclatasvir dose would need to be adjusted in most of these). Ledipasvir could be administered without significant DDI in 75%; Simeprevir- or 3D-based therapy could be used in less than 50%. One third of the subjects showed anemia that is a minor contraindication to RBV. Thus, in most of our PLHIV candidates for oral anti-HCV therapy the number of treatment options is limited unless cART is modified.