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Paper Poster Session
Hepatitis C management focussing on new antivirals

Safety and efficacy of DAA therapy in non-genotype 1 HIV/HCV patients in clinical practice

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Background: IFN-free, direct antiviral agents (DAA)-based therapy has shown high efficacy across all HCV genotypes, but there is still little information on its effectiveness in non-genotype 1 (G1)-HCV/HIV-coinfected patients in the clinical setting.

Material/methods: From an ongoing cohort of 298 HIV/HCV co-infected subjects starting DAA-based therapy at a tertiary center in Madrid, Spain, from April 2013, we selected non-G1 HCV subjects with at least SVR4 data (N=50), which represent 34% of those with complete data to date (N=149).

Results: Overall distribution of HCV genotypes: G2 2% (n=1), G3 36% (n=18), G4 62% (n=31). Most subjects were male (n=42, 84%), median age 51 (34-62), 76% cirrhotic (n=38), 26 non-naïve (52%), and non-CC IL28B genotype in 60% (n=30). HIV RNA was <50 copies/ml in all, median CD4 counts 492 cells/ml (64-1254). Baseline HCV-RNA was below $6x10^6$ IU/ml in 42 (84%). A 12w course of therapy was used in 28 (56%), and 20 received RBV (40%), median dose 13mg/kg/day (9-16). The most frequently used regimen was SOF/DCV (n=23, 46%), followed by SOF/LDV (15, 30%). Patients with HCV-G3 received SOF/DCV in 78% (n=14) -with RBV in 50%-, whereas among HCV-G4 subjects SOF/LDV was used in 39% (n=12), without RBV in all, and 9 subjects (29%) received SMV-containing regimens: 24w of SMV/DCV/RBV in 4, and 12w of SOF/SMV in 5 (with RBV in 2). The overall rates of RVR and RVS were: ITT 52% and 82%; OTT 56% and 91%). According to HCV genotype, RVS (ITT and OTT) were: G2 (100% and 100%; G3 89% and 100%; G4 77% and 85%. According DAA regimen, RVS rates (ITT) were: SOF/RBV 100% (1/1), SOF/DCV 100% (23/23), OMBITASVIR/PARITAPREVIR/RTV/RBV 100% (2/2), SOF/LDV 87% (13/15), SOF/SMV 20% (1/5), and SMV/DCV/RBV 25% (1/4). OTT analysis increased SVR rates only in SOF/LDV patients (100%, 13/13)). By univariate analysis, RBV use (70% vs 90%, p=0,13), 12 vs 24w (86% vs 74%, p=0,4), previous therapy (81% vs 83%, p=1), or HCV RNA over $6x10^6$ IU/ml (100% vs 79%, p=0,32) did not influence the rates of SVR. Only SMV-including regimens were associated to significantly worse outcomes in HCV-G4 subjects (p=0.0001). The overall rate of premature discontiuation was 16% (N=8), related to toxicity in only one (RBV-anemia). Among patients receiving RBV, dose adjustments were performed in 50% (n=10).

Conclusions: Among non-G1 HCV/HIV-coinfected patients, only SMV-including DAA therapy in HCV-

G4 was associated to treatment failure.Previous therapy, baseline HCV RNA, RBV use or treatment duration did not influence our high rates of SVR.