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Poster Session VI
Viral hepatitis and HIV/HCV co-infection

SAFETY AND ANTI-HCV EFFICACY OF AN IFN-FREE, SOFOSBUVIR PLUS RIBAVIRIN THERAPY IN HIV/HCV-COINFECTED PATIENTS AFTER LIVER TRANSPLANTATION

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Objective and Methods: to describe for the first time the safety and anti-HCV efficacy of the combination of sofosbuvir (SFB) -a new direct antiviral agent against HCV targeting the HCV-NS5B polymerase- plus ribavirin (RBV) in 5 HIV/HCV-coinfected patients with HCV recurrence after liver transplantation (LT).

Results: Mean age 50±8, female 60%, 80% prior AIDS. 80% HCV-G1 (n=4), HCV-G3 (n=1), 80% previously treated, 75% null responders to standard peg-IFN/RBV. All showed histological severity: cirrhosis 60% (n=3), (40%, n=2, fibrosing cholestatic hepatitis (FCH), both female with HCV-G1). 80% were on tacrolimus-based immunosuppresive therapy, 60% received steroids. All patients were on raltegravir-based HAART: 3 with KIVEXA™ (fixed dose 3TC/Abacavir), 2 with TRUVADA™ (fixed dose FTC/Tenofovir). Median time from LT to therapy was 488d (88-1031), and three (60%) have already completed 12 weeks (34w in P1). Median baseline HCV-RNA was 5,82 $\log_{10}$IU/ml. Median HCV-RNA decreases during therapy: w+2, -3,94$\log_{10}$IU/ml, w+4, -4,64$\log_{10}$IU/ml, 100% RVR (<15 IU/ml at w4). During therapy (median 12w) there were no cases of HCV-RNA or HIV-RNA rebound. Median initial dose of RBV was 800mg/d, with dose adjustments and blood transfusions needed in the two patients with FCH (40%). Liver transaminases and bilirubin reached normal values in 100%. There were not premature discontinuations, infections, deaths or SFB-related adverse events.
Conclusions: an IFN-free, SFB plus RBV regimen showed an excellent safety and efficacy profile in HIV/HCV-coinfected patients with HCV recurrence after LT. The observed rate of RVR was 100%, and all subjects normalized liver function tests. Viral response was obtained regardless baseline HCV-RNA, histological severity, HCV genotype, or previous pattern of response to standard peg-IFN/RBV