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DASABUVIR AND OMBITASVIR/PARITAPREVIR/RITONAVIR WITH OR WITHOUT RIBAVIRIN IN PATIENTS WITH HIV-HCV COINFECTION: REAL LIFE INTERIM ANALYSIS OF AN ITALIAN MULTICENTRE COMPASSIONATE USE PROGRAM

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Background and Aims: An HCV cure is now possible in a large proportion of HIV-HCV patient. We present real life results of a compassionate use program promoted by SIMIT (Infectious and Tropical Diseases Italian Society) of Dasabuvir and Ombitasvir/Paritaprevir/Ritonavir ± Ribavirin for 12 weeks in 213 HIV-HCV genotype 1 patients. Data on efficacy and tolerability of this strategy in HIV patients have been reported until now only in 43 non cirrhotic HIV subjects.
Methods: 213 HIV-HCV patients (female 26.3%, male 73.7%, median age 52, 25–77) from 26 Italian Infectious Diseases Clinics accessed the compassionate use of Dasabuvir and Ombitasvir/Paritaprevir/Ritonavir from March 2014. Ribavirin was added according to HCV genotype and patient's tolerability. Fibroscan was used to assess liver fibrosis (205 patients: F1–F2 77.5%, F3–F4 22.5%). Laboratory tests (HIV-HCV VL, biochemistry, CD4-CD8 count) were performed at Baseline, during and after treatment (Week4-8-12, Follow-Up 4-12-24).
Results: HAART was modified at baseline in 58% patients according to drug interactions. At Week 4, 84.5% (164/192) patients had HCV-RNA < 25 UI/mL (63.4% had HCV-RNA undetectable). At Week 8, 96.8% (154/159) had HCV-RNA < 25 UI/mL (81.8% undetectable). At Week 12, 99% of the patients (192/194) had HCV-RNA < 25 UI/mL most of them undetectable (97.9%). Analyzing the number of patients with detectable/undetectable HCV-RNA during Week 4, 8 and 12, a significant higher proportion was undetectable ($p < 0.001$). SVR4 data were available for 101 patients: all of them had HCV-RNA < 25 UI/mL (99% was undetectable). At ITT analysis SVR4 was 95.2%. One patient was lost to Follow-Up before Week4 and one patient spontaneously stopped treatment at Week 8 with HCV-RNA undetectable. Ribavirin doses of 15 and 10 pts were decreased at Week 4 and 8, respectively, and the treatment of one patient was suspended (Week 4). As regards HIV, at the EOT, 5 patients experienced viral failure (they were viremic at Baseline too); a comparison between Baseline and EOT HIV VL showed that the number of patients with undetectable HIV-RNA was higher at Week 12 compared to Baseline, with a trend towards statistical significance ($p = 0.05$). No serious adverse events were detected.
Conclusions: At the EOT, HCV-RNA was suppressed in 99% of HIV-HCV patients treated with Dasabuvir and Ombitasvir/Paritaprevir/Ritonavir ± Ribavirin. Treatment was generally well tolerated, compatible with a wide range of antiretrovirals and didn't compromise HIV control.

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C-SWIFT RETREATMENT FINAL RESULTS: HIGHLY SUCCESSFUL RETREATMENT OF GT1-INFECTED PATIENTS WITH 12 WEEKS OF ELBASVIR/GRAZOPREVIR PLUS SOFOSBUVIR AND RIBAVIRIN AFTER FAILURE OF SHORT-DURATION ALL-ORAL THERAPY

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Background and Aims: Therapies to retreat patients who have failed prior all-oral, direct-acting antiviral therapies have not been defined. The purpose of this study was to assess a retreatment regimen for subjects who had failed therapy with elbasvir/grazoprevir (EBR/GZR, an NS5A inhibitor + potent NS3/4A protease inhibitor fixed-dose combination) + sofosbuvir (SOF).
Methods: Genotype 1-infected patients who relapsed after therapy with EBR/GZR + SOF for 4, 6 or 8 weeks were offered retreatment with 12 weeks of EBR/GZR + SOF + ribavirin (RBV). The primary endpoint was the proportion of patients achieving hepatitis C virus RNA < 15 IU/mL 12 weeks after end of treatment (SVR12). Population sequencing was used to detect resistance-associated variants (RAVs) in NS3, NS5A and NS5B.
Results: Twenty-five of 29 eligible patients were enrolled: 88% (22/25) with G1a infection; 20% (5/25) with cirrhosis; baseline viral load mean 6.6 $\log_{10}$ IU/mL (range: 4.3–7.4 $\log_{10}$ IU/mL). At baseline of retreatment, 80% (20/25) patients had NS5A RAVs, 52% (13/25) had an NS3 RAV and 0/25 had an NS5B RAV. NS5A variants at the following positions occurred in 16–32% of the retreatment population, M28, Q30, L31, H58 and Y93. Nine subjects had both an NS5A and NS3 RAV at baseline. Twenty-three of 25 subjects completed therapy. Two patients were lost to follow-up; one after treatment day 3 and one after treatment week 4, at which time viral load was 363 IU/mL and target not detected, respectively. SVR12 was achieved in 100% of the 23 patients who completed therapy. One patient discontinued RBV only due to pruritus. Rash, fatigue and nausea were the most frequent adverse events occurring in 8% of patients.
Conclusions: 100% SVR12 was achieved with a 12-week regimen of EBR/GZR + SOF + RBV regardless of cirrhosis and high prevalence of RAVs (including two class RAVs). Final SVR24 results will be presented.