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Effectiveness, safety/tolerability of OBV/PTV/r ± DSV in patients with HCV genotype 1 or 4 with/without HIV-1 co-infection, chronic kidney disease (CKD) stage IIIb/V and dialysis in Spanish clinical practice – preliminary data Vie-KinD study

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Background and Aims:
Up to the date, limited data are available on the effectiveness and tolerability of DAA therapies for HCV-infected patients with severe CKD including those under hemodialysis. We aim to describe the effectiveness of OBV/PTV/r ± DSV (3D/2D regimen) with or without ribavirin (RBV) in HCV or HCV/HIV co- infected patients with GT1/GT4 and CKD (IIIb-V stages) in routine clinical practice in Spanish centers.
Methods: Non-interventional, retrospective, multicentric data col- lection in 24 Spanish sites. Socio-demographic, clinical variables, study treatment characteristics, effectiveness and tolerability data were collected from medical records.
Results: Upto date 119 patients with a mean age (SD) 58.2 (11.6) years were analysed. 92.7% GT1 (83.3% GT1b and 15.7% GT1a) and 7.3% GT4; 11 out of 119 (9.2%) HIV/HCV co-infected. 20.2% with fibrosis F3 and 26.9% F4 by fibroscan; 22.9% null responders and 31.4% partial responders to previous antiviral therapy. 9.2%, 16.8% and 73.9% of patients had CKD stage IIIb, IV and V respectively. 68.9% haemodialyzed; 5.9% peritoneal dialyzed and 39.5% with history of renal transplant. 86.6% of patients had comorbidities and concomitants diseases. 105 (88.2%) treated with 3D, 14 (11.8%) with 2D and 27.1% received RBV.
The overall sustained virologic response (SVR12) was 94.1% (112/119). The SVR12 rates by group were: HCV mono-infected (93.5%), HCV/ HIV co-infected (100%), GT1 (93.1%), GT4 (100%), CKD stage IIIb (81.8%), stage IV (95%) and stage V (95.5%). There were no virologic failures. 3 patients had missing data and 4 patients discontinued 3D/ 2D regimen: 2 due to adverse events (1.7%) and 2 died (1.7%). Only 7 patients (5.9%) experienced severe adverse events.
There was no significant difference between the eGFR level at the end of treatment (p = 0.117) and at 12 weeks after treatment (p = 0.875) at overall neither for renal stages IIIb, IV and V compared to baseline (± RBV) (Figure 1)
Conclusions: Preliminary results have shown that 3D/2D regimens are effective and tolerable in patients with end-stage chronic kidney disease including those in dialysis with genotype 1 or 4 chronic HCV mono-infection and HIV/HCV co-infection. The overall sustained virologic response (SVR12) was 94.1% without changes in eGFR evolution until 12 weeks post-treatment. These results are consistent with the ones observed in the clinical trials. Final analysis is required to validate these preliminary results.