Efficacy and safety of HCV-treatment with direct-acting antiviral agents interferon-free, in patients with severe renal impairment in clinical practice

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Background and Aims: Chronic hepatitis C virus infection (CHC) increases the risk of death in patients with chronic kidney disease (CKD) stage 4 – 5. However, patients with hepatitis C and CKD are considered a special population who are difficult to treat, and information about the efficacy and safety of IFN -free treatment regimens is limited. The aim of this study is to analyze the effectiveness and safety of the free IFN therapy in a large number of patients with CHC and CKD in clinical practice in Spain.

Methods: We carried out an observational, ambispective, multicenter study that included 1,343 Hep-C patients from the Spanish Association for the Study of the Liver (AEEH) database. Among those patients, 100 have advanced CKD data: 45 patients are stage 3b(Cl cret 30 – 44 mL/min),18 are stage4 (Cl cret 15 – 30 mL/min) and 37 are stage 5 (Cl cret <15 mL/min, with/without hemodialysis). All patients began treatment before October 2015. Demographic, clinical, virological, pretreatment type, antiviral regimen and renal function variables were analyzed.

Results: Patients with CKD were mostly men (74%) with a mean age of 57.6 years. Of the 100 patients, only 33 (33%) had undergone a previous antiviral therapy, compared with 760 (61.3%) patients without CKD ($p < 0.001$). Genotype distribution: G1 (86%); G3 (5%); G4 (9%). Fibrosis distribution: F0-F1: 22/F2-F3: 28/F4: 50. CKD patients were treated with SOF + SIM + RBV (8), SOF + LDV + RBV (16), SOF + DCV + RBV (16;), SIM + DCV + RBV (48), 3D Abbvie + RBV (9) SOF + RBV (3). The SVR4 (CKD 35/39; 89.7%) and SVR12 (42/47; 89.3%) were similar to patients without CKD (405/449; 90.2%). Dependant on the type of treatment, the SVR12 was: SOF + SIM +/ − RBV (7/8; 87.5%), SOF + LDV +/ − RBV (2/2, 100%), SOF + DCV +/ − RBV (16/16; 100%), SIM + DCV +/ − RBV (14/17; 82.3%), 3D Abbvie (1/1; 100%) SOF + RBV (2/3; 66,6%). SVR was lower in patients with cirrhosis (19/22, 86.3%) than in the rest of the cohort (18/18; 100%; $p = 0.024$). The stage of CKD did not influence the possibility of obtaining an SVR. Similarly, the SVR was independent of the CV [N1], genotype, duration of therapy, and whether or not RBV was used. No significant safety problems occurred, however treatment was discontinued in two patients due to a progression in renal impairment.

Conclusions: This multicenter clinical practice study demonstrates the remarkable effectiveness and safety of the combination of different IFN-free regimens in patients with CHC and CKD.