

MULTICENTER BELGIAN EXPERIENCE OF SOFOSBUVIR (MEDICAL NEED PROGRAM) IN VERY DIFFICULT-TO-TREAT HCV PATIENTS : SAFETY AND EFFICACY RESULTS. D. Degré (1), W. Laleman (2), X. Verhelst (3), A. Lamproye (4), T. Vanwolleghem (5), T. Gustot (6), P. Starkel (7), N. Lanthier (7), P. Michielsens (5), J. Delwaide (4), H. Vanvlierberghe (3), F. Nevens (2), C. Moreno (6). (1) CUB Hôpital Erasme, Brussels, Belgium, Department of Gastroenterology, Hepatopancreatology, and Digestive Oncology ; (2) University Hospitals Leuven, Leuven, Belgium, Department of Liver and Biliopancreatic disorders ; (3) UZ Gent, Gent, Belgium, Department of Hepatogastroenterology ; (4) CHU Sart Tilman, Liège, Belgium, Department of Hepatogastroenterology ; (5) UZ Antwerpen, Edegem, Belgium, Department of Gastroenterology and Hepatology ; (6) CUB Hôpital Erasme, Brussels, Belgium, Department of Gastroenterology, Hepatopancreatology and Digestive Oncology ; (7) UCL, Cliniques Universitaires Saint-Luc, Woluwe-Saint-Lambert, Belgium, Department of Gastroenterology.

Introduction : Severe hepatitis C (HCV) recurrence after liver transplantation (LT), HCV in cirrhotic patients listed for LT, and HCV in patients with severe extra-hepatic manifestations have a negative impact on patient survival and current treatment options are clearly suboptimal. Sofosbuvir (SOF), Daclatasvir (DCV) and Simeprevir (SMV) have been recently approved in Europe but there are limited data on the use of these drugs in the treatment of very difficult-to-treat patients with severe HCV.

Aim : The aim of this study was to evaluate the safety and efficacy of SOF treatment in combination with DCV, SMV, ribavirin (RBV) or Peginterferon (PegIFN) in very difficult-to-treat HCV patients.

Methods : We performed a retrospective analysis of patients with either severe HCV recurrence after LT, listed for LT or having severe extra-hepatic manifestations receiving SOF with SMV, DCV, Peginterferon (PegIFN) + ribavirin (RBV) or RBV in compassionate use or medical need in Belgium.

Results : 42 patients were enrolled in this data collection : 14 cirrhotics listed for LT, 17 LT recipients with severe recurrence, 8 with severe extra-hepatic manifestations, 2 decompensated cirrhotic patients, 1 cirrhotic IFN ineligible patient. Twenty-five patients had clinical liver decompensation. SOF was administered in combination with SMV, DCV and RBV alone in 9, 17 and 5 cases, respectively. Four patients received SOF, DCV and RBV. SOF was administrated with PegIFN and RBV in 3 cases. The majority of the patients were male (72.5%). Median age was 55 [51.2-66.7] years. Genotype distribution was : genotype 1 (n = 34), 2 (n = 1), 3 (n = 6) or 5 (n = 1). In listed for LT and post-LT patients, median MELD and Child-Pugh scores were 13.7 [10.1-19.5] and 8 [5.5-10], respectively. At baseline, 16 patients of them had ascites and 4 of them hepatic encephalopathy. Six patients have completed the treatment course and 31 are still on therapy. W4 and W12 HCV RNA undetectable was 20% (4/20) and 71,4% (10/14) respectively. End of treatment response was 100% (5/5) (1 viral load is ongoing) and SVR12 was 100% (2/2). Final SVR results will be presented. Treatment was stopped in 5 patients. Four patients were transplanted, viral load after LT was positive in 1 patient and currently unknown for the 3 others. SAEs were reported in 3 patients, 2 (hospitalization for flu-like syndrome and hyperkalemia) were not related to the antiviral treatment and 1 patient developed pancytopenia after 1 day of treatment (SOF+RBV) and the treatment was stopped.

Conclusions : This preliminary experience in very difficult to treat patients shows that SOF in combination with DCV, SMV, RBV or PegIFN is safe and virological response seems to be promising.