Sofosbuvir/Ledipasvir plus Ribavirin achieves high SVR12 in genotype-3 patients with compensated cirrhosis and similar to Sofosbuvir plus Daclatasvir. A multicentre real life cohort

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Background and aims: Current antiviral therapy for HCV genotype (GT) 3-associated cirrhosis achieves suboptimal sustained virological response (SVR) rates. Daclatasvir (DCV) + Sofosbuvir (SOF) ± ribavirin (RBV) is the only all-oral recommended option due to lower SVR rates of SOF/LDV in patients with cirrhosis. We aimed to evaluate the efficacy and safety of 12 and 24-week SOF+DCV or SOF/LDV ± RBV in a real-life cohort of GT3 patients with cirrhosis.

Patients and methods: Multicenter observational study from two different databases: HepaC-AEEH and Community of Madrid Regional registry. All HCV-cirrhotic patients mono-infected by GT3 and treated with SOF plus a NS5A inhibitor (DCV or LDV) ± RBV between May 2014 and October 2015 were included.

Results: 282 patients were included: 83% male, age 54 years (26-82), 124 (44%) treatment-experienced, 48 (17%) decompensated, 130 (46%) FibroScan >20 kPa and 65 (23%) MELD score>10.195 (69%) received SOF+DCV and 87 (31%) SOF/LDV. Over-all, 88% received RBV. The addition of RBV and extension to 24 weeks were higher in the SOF/LDV group (95% vs. 84%, *p*=0.004; 83% vs. 62%, p<0.001). A higher percentage of decompensated patients were treated with DCV (21% vs. 10%, p=0.029). 208 patients have reached week 12 of follow-up. Overall SVR12 was 93.8% (195/208), 94% with SOF+DCV and 93.5% with SOF/LDV. SVR12 rates are summarized in table. 13 failures were observed (9 relapses, 1 virological failure, 3 deaths). Previous treatment did not impact on SVR. Platelet <75,000/mL was the only factor associated with nonSVR12 (RR: 3.50; 95%CI 1,23-9,94; p=0.019). In patients with MELD <10 or albumin >3.5 mg/dL, type of NS5A inhibitor did not impact on SVR12 (93% vs 97%, RR 0.96, 95%CI 0.89-1.04; 93% vs 96%, RR 0.97, 95%CI 0.90-1.05, respectively). Only 16 patients (5.7%) presented serious adverse events (SAE), including 3 deaths (1.1%) and 6 discontinuations

(3.2%). Percentage of SAEs and deaths was higher in decompensated patients (18% vs. 3.1%, p<0.001, 4% vs. 0.4%, p=0.08). SVR12 of all cohort will be presented at the meeting.

Conclusions: SOF/LDV+RBV achieved high SVR12 rates in GT3 patients with compensated cirrhosis, similar to SOF+DCV, both with low rates of serious adverse events.

		SVR n (%)	95 CI
SOF+DCV+RBV	Child A	82/87 (94,2%)	0,87-0,98
SOF+DCV+RBV	Child B/C	17/18 (94,4%)	0,72-0,99
SOF+DCV	Child A	10/11 (91,0%)	0,58-0,99
SOF+DCV	Child B/C	14/15 (93,3%)	0,68-0,99
SOF/LDV+RBV	Child A	61/64 (95,3%)	0,86-0,99
SOF/LDV+RBV	Child B/C	7/9 (77,7%)	0,39-0,97
SOF/LDV	Child A	4/4 (100%)	0,39-1
SOF/LDV	Child B/C	0/0	NA

Disclosures:
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