Background

New direct antiviral agents (DAAs) have shown a great efficiency and safety in clinical trials and cohorts. However, the number of cirrhotic HCV-infected patients included in most of these studies is small.

Methods and objectives

Multicenter prospective cohort analysis carried-out in 13 Spanish hospitals between January and December 2015. Inclusion criteria: 1) Adult patients (>18 years old) 2) Cirrhosis diagnosed by transient elastography (TE=14.6kPa) or by sonographic, endoscopic and/or clinical data. 3) HCV treatment based on DAAs according to drug availability and physician discretion. 4) HCV/HIV coinfection with stable ART and controlled HIV infection.

Primary endpoint: Overall efficacy (percentage of patients with undetectable HCV-RNA at week 12 after treatment - SVR12).

Secondary endpoints: Safety (percentage of withdrawal due to toxicity and/or hepatic decompensation) and efficacy according to regimen used and HCV genotype. Change in TE after HCV treatment was also evaluated.

Results

- 170 patients analyzed (Table 1). Mean TE 20.6kPa (IQR 16.1-33.7).
- Genotype distribution: GT-1α, 68 (40%); GT-1b, 21 (12.4%); GT-4, 47 (27.6), GT-3, 26 (15.3%) y GT-2, 1 (0.6%)
- Overall, 92.9% (158/170) SVR12 rate, without differences between genotypes (Table 2).
- Lower SVR12 rate in treatment-experienced patients (88.8% vs. 97.5%, p=0.067) driven by a poorer SVR12 among pretreated patients with GT-1α (87.2% vs. 100%; p=0.045) (Figure 1).
- Causes of failure: 7 (4.1%) relapses, 2 (1.2%) lost to follow-up, 1 (0.6%) toxicity, 1 (0.6%) hepatic decompensation and 1 (0.6%) viral breakthrough.
- Patients with relapse after HCV treatment are summarized in table 3. Twenty (16.3%) patients treated with RBV needed dose modification, mainly due to anemia (n=17).
- On-treatment hepatic decompensation was observed in 4 (2.4%) patients (2 encephalopathy and 2 ascites).
- TE a week 12 after treatment finalization decreased a mean of 5.6 kPa (95CI 1.8-9.2; p=0.004) as compared with baseline.

Conclusions

In our cohort of HCV-infected patients complicated cirrhosis, treatment with DAAs-based combinations was highly safety and efficacious. Viral eradication was associated with a significant decrease in liver stiffness.

Our data reinforces current recommendations to treat HCV-infected patients with the same regimens as HCV monoinfected patients.