BINARY LOGISTIC REGRESSION ANALYSIS TO EVALUATE THE INFLUENCE OF DIFFERENT BASAL FACTORS ON THE EFFECTIVENESS OF LEDIPASVIR/SOFOSBUVIR.

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BACKGROUND

Chronic hepatitis C treatment has changed with the commercialisation of direct-acting antivirals (DAAs) for the hepatitis C virus (HCV) with high levels of safety and effectiveness. Available data from clinical trials reveal that baseline factors at the beginning of treatment that can influence treatment results are viral genotype, baseline viral load, degree of fibrosis and previous treatments.

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PURPOSE

To assess the influence of different variables on the effectiveness of the combination Sofosbuvir (SOF) and Ledipasvir (LDV) in HCV patients.

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MATERIAL AND METHODS

- Retrospective-observational study.
- Study period: April 2015-February 2016.
- Inclusion criteria: Patients with HCV infection treated with SOF/LDV for 12 weeks.
- o Exclusion Criteria: Patients with no data available.
- Outcomes collected:
 - Demographics: age/sex.
 - Clinical data: basal viral load (VL), sustained virological response at week 12 (SVR12), METAVIR score. Livertransplant, HCV genotype (G), HIV co-infection, previous treatments for HCV.
- Logistic regressions were used to identify independent clinical and demographic predictors of treatment failure.
- o SPSS v.17.
- Significance level of 0.05.

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RESULTS

124 patients

Men: 65.6% , Age: 56.67±10.07

o **Naïve:** 60.7%

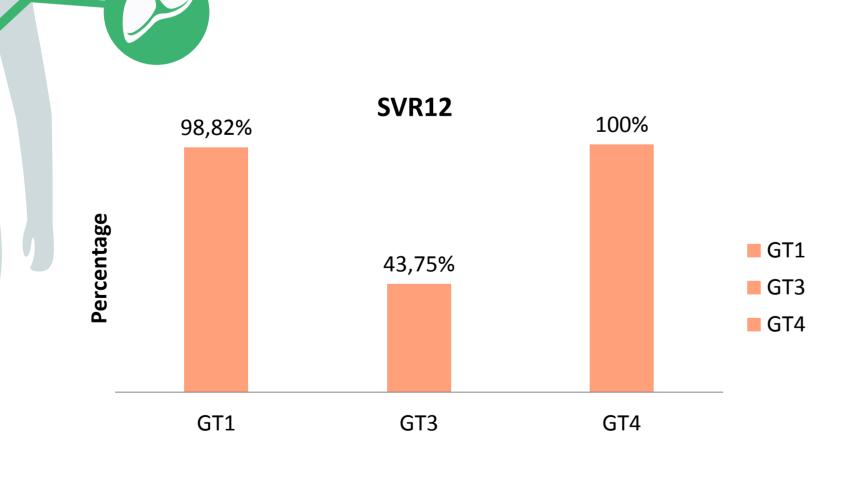
HIV-coinfected: 25.4%

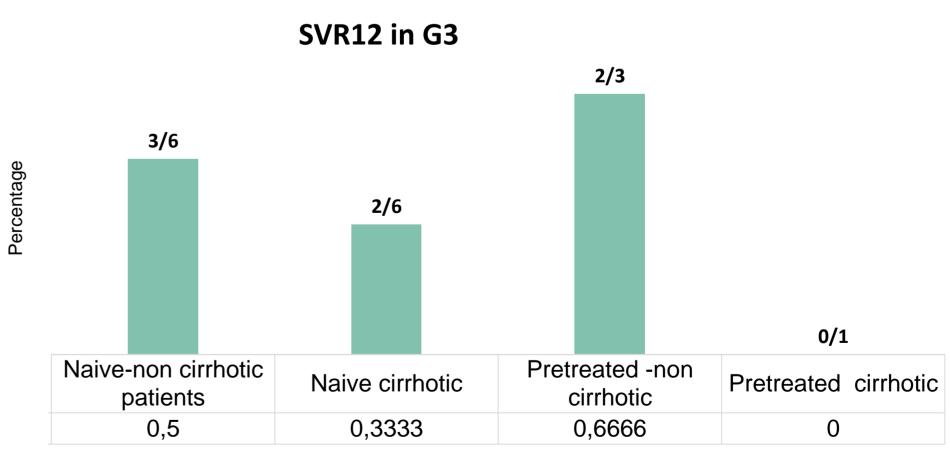
Liver-transplant: 14.8%

HCV genotypes: 9.68% G1; 23.38% G1a; 37.10% G1b; 12.90% G3; 16.94% G4

o VL>800,000UI/ml: 63.9%

o **Fibrosis degree:** 6.6% F1, 26.2% F2, 33.6% F3 and 33.6% F4





Global SVR12 was 91.67% and all patients with HCV G1a, G1b, G4 achieved SVR12.

Only one pre-treated non-cirrhotic HCV G1 patients relapsed.

The SVR12 for G3 (43.75%): 50% (n=3) naive-non-cirrhotic achieved SVR12 and nobody of pre-treated-cirrhotic achieved SVR12.

None of the variables analyzed significantly influenced on SVR12, except G (p=0.001). Almost all the relapses occurred in G3.

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CONCLUSION



It has been observed that G3 influenced on SVR12, and LDV is less active against G3 in-vitro. Other variables analyzed didn't influence on SVR12.