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REAL WORLD EVIDENCE OF THE EFFECTIVENESS AND CLINICAL PRACTICE USE OF GLECAPREVIR PLUS PIBRENTASVIR (G/P) IN PATIENTS WITH CHRONIC HEPATITIS C GENOTYPES 1 TO 6 IN PORTUGAL – FINAL RESULTS OF THE RESPONSE STUDY

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INTRODUCTION

- There are no published studies about the safety and effectiveness of G/P in Portuguese clinical practice. This study aims to close this gap.
- **The objective of this study was to describe, in the Portuguese routine clinical practice, the effectiveness of G/P**

MATERIAL/METHODS

- **Study design:** Prospective, multi-center observational study in patients with Chronic C Hepatitis receiving the G/P in Portuguese routine clinical practice;
- **Study centers:**
  - North of Portugal: *Centro Hospitalar Universitário Porto*; *Centro Hospitalar Vila Nova de Gaia/Espinho*;
  - South of Portugal*: Centro Hospitalar Barreiro-Montijo; Hospital Garcia de Orta; Centro Hospitalar Universitário de Lisboa Central; Centro Hospitalar Universitário Lisboa Norte.*
- **Population:** treatment-naïve (TN) or PegINF/RBV/SOF experienced (TE) adults with confirmed chronic hepatitis C, GT1-6, with or without compensated cirrhosis. The prescription of a G/P was at the discretion of the physician in accordance with local clinical practice, international guidelines and/or label, **predating regulatory approval of 8 weeks treatment for treatment naïve**;
- **Primary endpoint:** percentage of patients achieving SVR12 (defined as HCV RNA <lower limit of quantification [LLoQ] 12 weeks [i.e. ≥70 days] after the last actual dose of G/P with a sensitive polymerase chain reaction test with an LLoQ of <50 IU/mL) overall and in subpopulations of interest.

RESULTS

Figure 1. Patient Selection

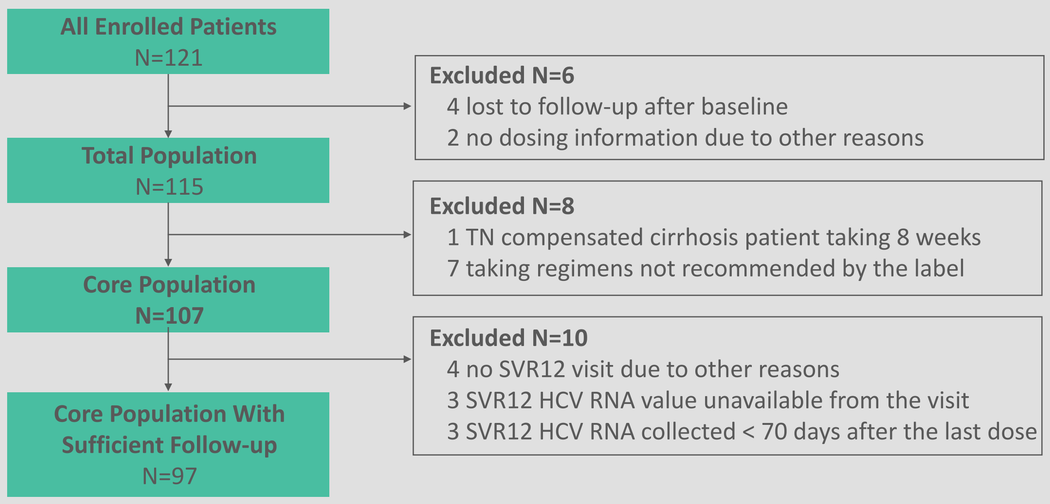


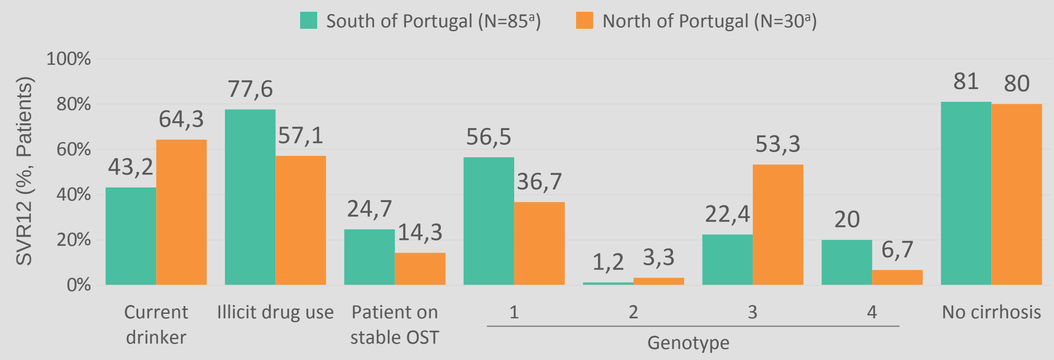
Table 1. Baseline characteristics of the Total Population

	Total Population N= 115
< 65 years old	109 (94.8)
Male	96 (83.5)
Current drinker	41/88 (46.6)
Former drinker	27/88 (30.7)
Illicit drug use (ever)	82/113 (72.6)
Current illicit drug use	12/113 (10.6)
On stable opiate substitution therapy	25/113 (22.1)
Treatment naïve[b]	106/113 (93.8)
HCV genotype	
1	59 (51.3)
2	2 (1.7)
3	35 (30.4)
4	19 (16.5)
5-6	0
No history of varices, decompensation, hepatorenal syndrome and/or HCC	113 (98.3)
Baseline fibrosis stage	
F0 - F1	54/79 (68.4)
F2	3/79 (3.8)
F3	6/79 (7.6)
F4	16/79 (20.3)

Data are n (%) [a]Number of patients in the total population was 115, unless stated otherwise; [b]No previous experience with DAAs, and with regimens based on SOF and IFN

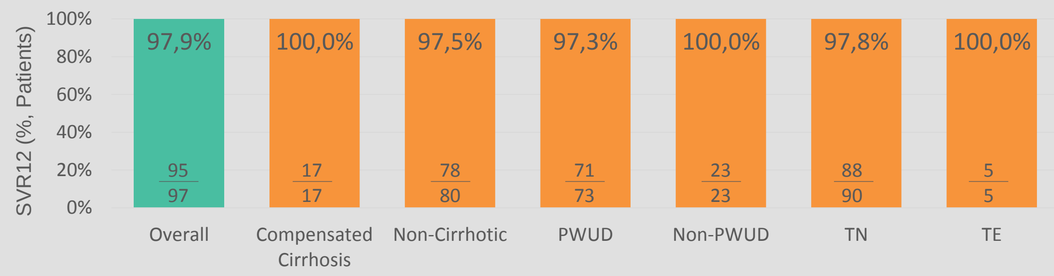
RESULTS (CONTINUED)

Figure 2. Regional characteristics of Total Population



[a]Different N from presented were reported for: current drinker North (N=74) and South (N=14); illicit drug use North (N=28); Patients on stable OST North (N=28)

Figure 3. SVR12 Rates With G/P in the Core Population With Sufficient Follow-up: Overall and by subgroups of interest



PWUDs, people who use drugs; TN, treatment-naïve; TE, PegINF/RBV/SOF experienced

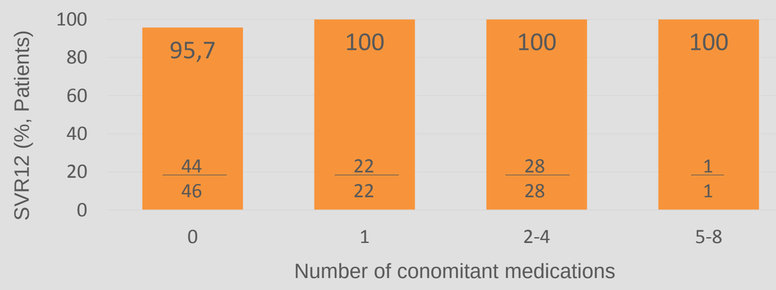
2 virological failures were reported in the Core Population With Sufficient Follow Up

Table 2. Adverse events and laboratory abnormalities with G/P

	Total Population N= 115
Subjects with AEs	
Any adverse event (AE)[a]	3 (2.6)
Any AE with a reasonable possibility of being related to DAAs	2 (1.7)
Any AE with a grade 3 or higher	1 (0.9)
Any DAA related AE with a grade 3 or higher	1 (0.9)
Any serious AE	0
Any AE leading to discontinuation of study drug	0
Any AE leading to interruption of study drug	1 (0.9)
Deaths	0
Laboratory abnormalities	
Post-nadir ALT >5 × ULN	0/47
Total bilirubin ≥2 × ULN	0/47

Data are n (%). [a]AEs were: headache n=2 (1.7%); vomiting n=2 (1.7%); fatigue n=1 (0.9%), and nausea n=1 (0.9%)

Figure 5. SVR12 Rates by number of concomitant medications for the Core Population With Sufficient Follow-up



CONCLUSIONS

- **G/P administered for 8 or 12 weeks was highly effective and well tolerated, and these results were consistent with previous reports (clinical trials and real word data studies);**
- SVR results were consistent, independently of the subgroup of interest (cirrhosis status, illicit drug use, and treatment experience) and number of concomitant medications;
- The characteristics of HCV infected patients seem to differ between the north and south of Portugal (i.e. genotypes, drugs and alcohol use – statistical analysis to be preformed)

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