Real-life efficacy and safety of Glecaprevir/Pibrentasvir in a large cohort of HCV-infected patients: the MISTRAL study

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Background

Data on the effectiveness and safety of Glecaprevir/Pibrentasvir (G/P) for the treatment of HCV infection in a 'field-practice' scenario are still scant. The MISTRAL (MavIret SouTh italy ReAl Life) study evaluates this therapeutic regimen in a large cohort of HCV-infected patients of Southern Italy.

Methods

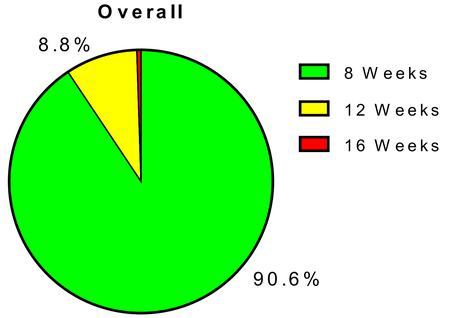
All consecutive HCV-infected patients treated from November 2017 to May 2018 with G/P in 22 liver centers of Southern Italy were enrolled. Patients with liver comorbidities were excluded. Patients' baseline features, the achievement of a sustained virologic response (SVR, undetectable HCV-RNA in patients' blood sample obtained twelve weeks after the end of therapy) and the presence of adverse event (AE) or serious adverse event (SAE) were collected in a dedicate dataset. Hepatic fibrosis was determined histologically or non-invasively, through liver stiffness measurement by mean of transient elastography.

Results

We enrolled 1178 subjects. Patients' baseline characteristics are shown in **Table 1**. Therapy duration was 8 weeks for the majority of patients (**Figure 1**). Data on sustained virological response are shown in **Figure 2**. Only 62 pts reported an AE and 8 pts a SAE (**Figure 3**).

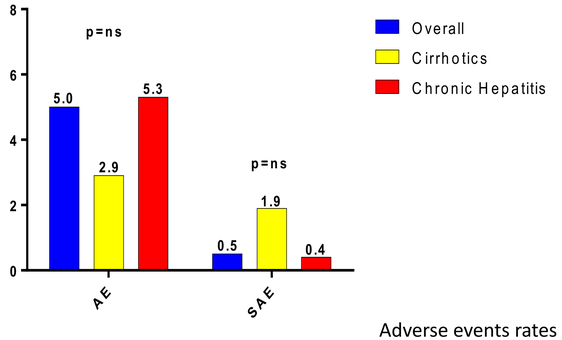
Table 1	Overall	Cirrhosis	Chronic Hepatitis	p
N of Patients (%)	1177	104 (8.8)	1048 (89,1)	-
Male Sex (%)	583 (49.5)	67 (64.4)	500 (47.7)	**0.001**
Age (±SD)	60.3 (±14.6)	64.7 (±13.2)	59.9 (±14.6)	**0.03**
Diabetes (%)	90 (7.6)	23 (22.1)	64 (6.1)	**< 0.0001**
Genotypes (%)				
1a	161 (13.7)	10 (9.6)	147 (14.0)	ns
1b	433 (36.8)	41 (39.4)	389 (37.1)	ns
2	406 (34.5)	33 (31.7)	364 (34.7)	ns
3	123 (10.5)	15 (14.4)	104 (9.9)	ns
4	48 (4.1)	5 (4.8)	42 (4.0)	ns
Metavir Score (%)				
F0/F1	745 (63.3)	-	745 (71.1)	-
F2	211 (17.9)	-	211 (20.1)	-
F3	92 (7.8)	-	92 (8.8)	-
F4	104 (8.8)	-	-	-
Stiffness (±SD) KPa	7.7 (±5.6)	20.9 (±11.6)	6.5 (±2.2)	**<0.0001**
ALT (±SD) U/L	56.2 (±54.7)	78.4 (±68.5)	53.6 (±52.0)	**< 0.0001**
Creatinin (±SD) mg/dl	1.02 (±1.18)	1.54 (±2.12)	0.96 (±1.01)	**< 0.0001**
Bilirubin (±SD) mg/dl	0.76 (±0.43)	0.87 (±0.39)	0.75 (±0.44)	**<0.0001**
Hemoglobin (±SD) g/dl	14.2 (±1.6)	13.8 (±2.0)	14.2 (±1.6)	**0,048**
Platelets (±SD) 10E3/µL	207 (±64)	156 (±69)	212 (±61)	**<0.0001**

Figure 1



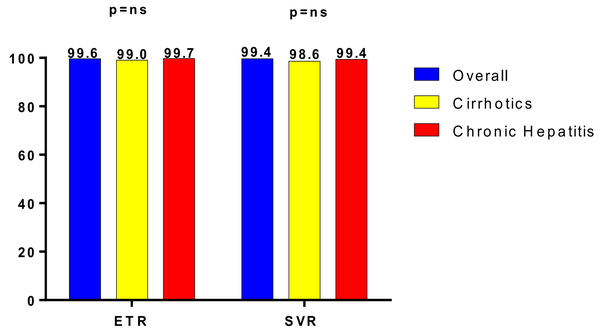
Treatment durations prevalence

Figure 3



Adverse events rates

Figure 2



Therapy response rates

Conclusions

The large MISTRAL study, conducted in a field-practice scenario, provides a still better prevalence, compared to registration trial, of SVR confirming the extraordinary efficacy and safety of Glecaprevir/Pibrentasvir association also for only 8 weeks treatment.