EFFECTIVENESS, SAFETY AND POTENTIAL INTERACTIONS OF ELBASVIR/GRAZOPREVIR FOR CHRONIC HEPATITIS C INFECTION

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Background

- Elbasvir/grazoprevir is a newly direct-acting antiviral combination indicated for the treatment of chronic HCV genotype 1 or 4 infection in patients with and without compensated cirrhosis.

Aim

To assess the effectiveness, safety and potential interactions of elbasvir/grazoprevir treatment in patients with HCV infection in routine clinical practice.

Methods

- Observational retrospective study in a tertiary hospital.
- Monoinfected adult patients with HCV infection treated with elbasvir/grazoprevir (E/G) in monotherapy between January and June 2017 were registered.
- Age, gender, ethnicity, hepatic fibrosis stage, prior HCV treatments, regular medication, adverse events (AE), HCV genotype, viral load (VL) at baseline, at treatment completion and 12 weeks after the end of treatment (EOT) were collected.
- Achieving sustained virologic response (SVR12), defined as undetectable HCV-RNA 12 weeks after treatment completion, was considered effective.

Results

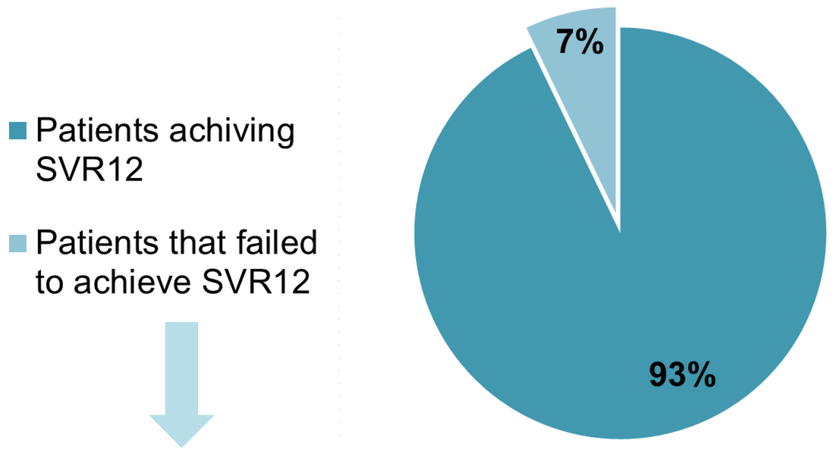
- Sixty patients completed treatment with E/G (Table1)

Table 1

Baseline Characteristics	
Mean age, years ± SD	63±12
Women, *n* (%)	34 (57%)
European, *n* (%)	58 (97%)
Naïve, *n* (%)	40 (66.7%)
HCV genotype, *n* (%)	
1b	53 (88%)
4	7 (12%)
Hepatic fibrosis stage, *n* (%)	
F0-F1	13 (21.7%)
F2	22 (36.7%)
F3	13 (21.7%)
F4	12 (20%)
Viral load at baseline (million IU / ml, mean)	2.96

- Forty-nine patients (**82%**) were regularly taking medication with an average of **5 drugs per patient**.
- **Potential interactions** were detected in 13 patients (**21.7%**), mostly with:
  - Amlodipine (n=4)
  - Statins (n=4)
  - Amiodarone (n=3)
  - Tacrolimus (n=2)
  - Colchicine (n=2)
- VL was undetectable in 57/60 patients (95%) at the EOT.
- SVR12 data were available for 42 patients (Fig.1)

Fig. 1. Treatment outcomes



Three patients: two, with genotype 1b, had viral breakthrough (one of them was reanalyzed and found to be 1a) and one discontinued due to renal transplant complications.

- Twenty-nine patients (**48.3%**) reported AE. Most described AE are presented below. (Table 2)

Table 2

Adverse Events	*n* (%)
Gastrointestinal disorders	8 (13.3%)
Arthralgia/myalgia	7 (11.7%)
Asthenia	6 (10%)
Headache	4 (6.7%)
Pruritus	3 (5%)
Alopecia	3 (5%)
Insomnia	2 (3,3%)

- Laboratory abnormalities were found in 2 patients, one with an increase of lipase and another with an increase of amylase and lipase values.

Conclusions

- Elbasvir/grazoprevir was effective; similar results of RVS12 were obtained in clinical trials.
- Adverse events were reported by approximately half of all patients.
- Elbasvir/grazoprevir may have clinically significant interactions.

Authors declare no conflict of interest

References

- Elbasvir/grazoprevir: Summary of product characteristics. EMA.