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SAFETY RESULTS OF DIRECT-ACTING ANTIVIRALS FOR THE TREATMENT OF HEPATITIS C VIRUS INFECTION

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OBJECTIVES

The recent development of drugs has changed radically the therapeutic of chronic hepatitis C virus (HCV) infection, from interferon (IFN)-based treatments to treatments based on Direct-Acting Antivirals (DAA). These drugs are supposed to be better tolerated; however, data are preliminary yet.

Objective: To evaluate the safety of DAA-based treatment of HCV in clinical practice.

METHODS

Design: An observational, descriptive and prospective study

Inclusion criteria: monoinfected patients started DAA-based treatments (free-IFN) between January 2014 and September 2015 (minimum 8-week follow-up period)

Variables

- Demographic and baseline clinical data
- Selected DAA combination
- Adverse drug events (ADE)*
- Discontinued treatments and deaths

DCV: daclatasvir
DSV: dasabuvir
LDV: ledipasvir
OTP: ombitasvir
PTV/r: paritaprevir/ritonavir
RBV: ribavirina
SMV: simeprevir
SOF: sofosbuvir

*Common Terminology Criteria for Adverse Events Classification (CTCAEv4)

RESULTS

499 patients

Table 1. Demographic/baseline clinical data

Genotype 1	87.4%
Gender (men)	62.1%
Age (years(SD))	58.8 (11.1)
Decompensated cirrhosis	9.8%

Figure 1. Fibrosis

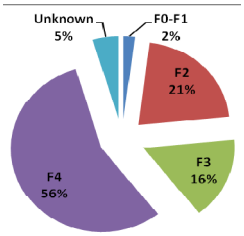

Figure 2. DAA combination

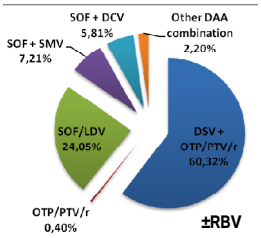

Table 2. Safety of DAA (±RBV)

DAA combination* (N)	Rare ADE (N;%)	Serious ADE grade 3/4 (N;%)	Discontinued treatments (N;%)	Deaths** (N;%)
SOF/LDV (120)	•Erythroderma (1; 0.83) •Significant weakness of low members and general deterioration (1; 0.83)	•Hyperbilirubinemia (3; 2.5) •Fatigue (3; 2.5) •Headache (1; 0.83) •Diarrhea (1; 0.83) •Muscle pain (1; 0.83) •Dry skin (1; 0.83)	•Patient decision •Generalized erythroderma •Extreme tiredness •Sgnificant weakness of low members and general deterioration	2; 1.67
DSV+OTV/PTV/r (301)	•Acute hepatitis (1; 0.33) •Priapism (1; 0.33) •Sweating (1; 0.33) •Syncope (1; 0.33)	•Hyperbilirubinemia (9; 2.99) •Fatigue (3; 1.00) •Confusion (2; 0.66) •Itching (2; 0.66) •Anemia (2; 0.66) •Vomiting (1; 0.33) •Diarrhea (1; 0.33) •Sleep disorders (1; 0.33) •Dyspnea (1; 0.33)	•Likely drug induced hepatitis •Patient decision •Previous dysphagia and inability to swallow the drug	1; 0.33
SOF+DCV (29)	-	•Hyperbilirubinemia (5; 17.24) •Sleep disorders (1; 3.45)	-	1; 0.33
SOF+SMV (36)	-	•Hyperbilirubinemia (5; 13.89)	-	2; 5.56

* Other DAA combinations in 13 patients
**Any death could be attributed to the treatment. All the patients suffered decompensate cirrhosis prior to DAA-treatment

CONCLUSIONS

The study data demonstrate that most combinations were well tolerated regardless of DAA combination. However, results suggest further research is needed to increase safety data and to improve detection of less frequent ADE.

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