SAFETY PROFILE OF THE NEW DIRECT ACTING ANTIVIRALS AGAINST HEPATITIS C VIRUS

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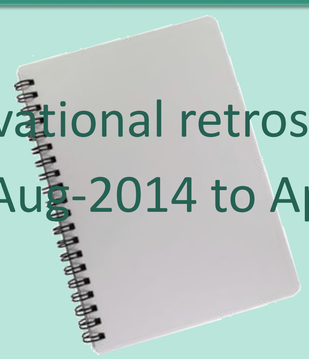
Objectives

1) Learning about aspects of the safety of simeprevir, sofosbuvir and daclatasvir
2) Detecting AEs not previously described for these drugs.

Material and methods



Observational retrospective study (Aug-2014 to Apr-2015)

- AEs registered in hepatitis C patients treated with simeprevir, sofosbuvir and/or daclatasvir
- Recorded data: age, sex, baseline laboratory values and FibroScan, viral genotype, pharmacotherapeutical information, referred EAs

Farmatools +

Results

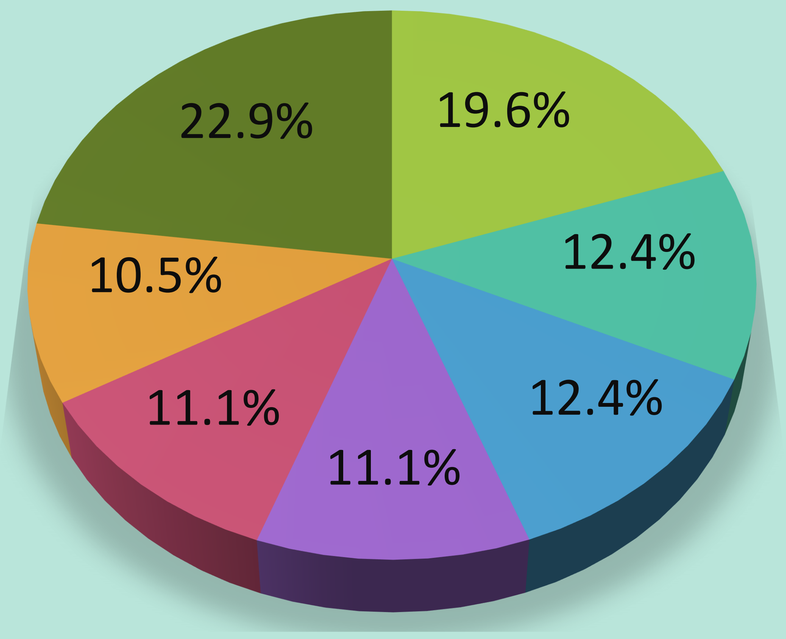
17/39 22/39

Average age: 52.2

FibroScan > 12 KPa	66.6%
Pre-treated patients	49.7%
Interferon and/or ribavirin free treatments	38.5%
Virus C genotype	1b (53.8%), 1a (15.4%), 1a/1b (2.6%), 2 (10.3%), 3 (12.8%), 4 (5.1%)

152 AEs registered → 53 different AEs

No patients had to be hospitalized or discontinue the therapy because of AEs



- Gastrointestinal disorders
- Skin and subcutáneous tissue disorders
- Nervous system disorders
- Blood and lymphatic system disorders
- Musculoskeletal and connective tissue disorders
- Psychiatric disorders
- Other disorders

Most prevalent AEs

Anaemia (41.1%)
Pruritus (38.5%)
Fatigue (28.2%)

Anaemia

- 97.4% grade 1, 2.6% grade 2
- associated to ribavirin-included treatments
- registered in a patient treated with sofosbuvir and daclatasvir

A higher incidence of anticholinergic AEs was observed when co-administering simeprevir and sofosbuvir.

AEs not previously reported for sofosbuvir + daclatasvir

Bone pain (2/39), urinary retention (2/39), osteochondritis (1/39)

Conclusion

Simeprevir, sofosbuvir, and daclatasvir seem to be safer than the previous direct acting antivirals used to treat hepatitis C. The most frequent and severe EAs are mainly due to ribavirin. Due to the low sample size, infrequent or rare AEs could not be detected. It would be useful extending the study to detect new AEs.

No conflict of interest

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