EPCLUSA-RELATED SLEEPINESS: A CASE REPORT

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5P-SQ-004

BACKGROUND AND IMPORTANCE

Epclusa (viral NS5A inhibitor Velpatasvir and Sofosbuvir) is used to treat patients with **Hepatitis C**. The treatment duration is 12 weeks for all genotypes and the cure rates are from 97% to 100% in patients without cirrhosis or with compensated cirrhosis.

Based on data obtained from Phase 3 clinical studies the percentage of patients who permanently **discontinued** treatment due to adverse events was **0.2%** and the percentage of patients experiencing any **serious adverse event was 3.2%**

AIM AND OBJECTIVES

To describe a case of a patient who is experiencing sleepiness while being treated with Epclusa, and to assess the potential link between treatment and the adverse event

MATERIAL AND METHODS

The patient is a **72-year-old woman** diagnosed with heapatitis C with **compensated cirrhosis** and who is treated with **Epclusa** (sofosbuvir/veltapasvir) in May 2022.

Home medication checked

- Omeprazole
- Metformine
- Hydrochlorothiazide
- Enalapril
- Lacosamide
- Levetiracetam
- Atorvastatine

Separate the omperazole 4 hours with the intake of epclusa

She was referred to the emergency department after presenting **sleepiness** and **general deterioration** after 16 days receiving treatment with Epclusa. As a result, she was diagnosed with regular cold and immediately after was treated with amoxicillin. She also suffer from constipation, which spontaneously resolved within two days. After evaluation, **it was decided to suspend Epclusa treatment**.

RESULTS

4 days after, she was referred to the hospital outpatient department when the family member reported **improvements in sleepiness after the treatment discontinuation**, although the iatrogenic origin cannot be guaranteed since it has also coincided with catarrhal symptoms and constipation, both situations ceased.

Naranjo's algorithms establish the causality relationship between the two (score of 2).

The spanish pharmacovigilance (RPC) center was notified. ✓

CONCLUSION AND RELEVANCE

The European Medicines Agency's (EMA) technical sheet for Epclusa does not include sleepiness as a frequent ADR. The RPC highlighted this case as the only Epclusa ADR notified in our country. The **reporting of ADRs at the hospital level** is fundamental as the in clinic- world real use of new innovative drugs is evolving based on these. Severe ADRs are most likely to be identified in hospitals and consistent monitoring is critical to **prevent future cases**