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SERIOUS ADVERSE REACTIONS AND SUSTAINED VIRAL RESPONSE RELATED TO 3D REGIME: PURPOSE OF A CASE

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Background

New hepatitis C virus (HCV) antivirals are characterized by their efficacy (achievement of sustained viral response (SVR)), and safety with remarkable adverse drug reactions (ADR), such us hepatic decompensation, hypersensitivity reactions or hyperbilirubinemia.

Purpose

Describe ADR, due to direct acting antivirals, not described so far.

Material and methods

Electronic medical records were reviewed: clinical and pharmacological history, and dispensations (collected from the outpatient dispensing software).

Results

- A 79-year-old woman with **chronic HCV genotype 1b infection**, currently in compensated cirrhotic phase, with excellent quality of life and without previous cardiovascular risk factors. No usual home treatment.
- In 2003, she was treated with double therapy (Interferon + Ribavirin), suspended after the first month of treatment due to severe anemia, without obtaining SVR (undetectable viral load, VL).
- Currently, she iniciate a combination therapy of **Ombitasvir/Paritaprevir/Ritonavir 12.5/75/50 mg 2 tablets/day, and Dasabuvir 250 mg 1 tablet/12 h**, known as 3D regimen, for 12 weeks, without associating ribavirin because of the risk of previous anemia. Initial VL was 1,120,000 copies/ml (6.04 log).
- After four weeks of treatment, she was admitted for congestive heart failure (CHF), hypoxemic respiratory insufficiency and acute respiratory alkalosis. She developed atrial fibrillation with rapid ventricular response, moderate pulmonary hypertension, and massive bilateral pleural effusion. In addition, he developed acute renal failure (with creatinine of 2.1 mg/dl) and direct hyperbilirubinemia (total bilirubin 5.8 mg/dl and direct bilirubin 4.8 mg/dl). Subsequently, she evolved favorably after antiviral drugs withdrawal, and with active and supportive treatment during admission, with the improvement of analytical values (creatinine 0.6 mg/dl, bilirubin 1.7 mg/dl). No microorganisms were isolated from the pleural fluid simple.
- At discharging, 5 weeks post-admission, and 24 weeks later, the patient maintained a SVR, despite receiving only **4 weeks of treatment**.

Conclusion

To date, there are no reported cases of patients who have developed CHF, severe pleural effusion and acute renal failure following the 3D regime instauration. This is the first described case of SVR after only 4 weeks of treatment with 3D triple therapy in patients with genotype 1b and F4 grade of fibrosis.

eahp european association of hospital pharmacists