CP-226

SAFETY OF DIRECT ACTING ANTIVIRAL AND ANTIRETROVIRALS DRUGS IN HCV PATIENTS CO-INFECTED WITH HIV-1: CLINICAL PRACTICE EXPERIENCE

Cañamares-Orbis I, Izquierdo-Garcia E, Esteban-Alba C, Such-Diaz A, Saez-DelaFuente J, Barrueco-Fernandez, Ryan P, Troya J, Escobar-Rodriguez I

Pharmacy Department, University Hospital Infanta Leonor, Madrid.

Background

The first oral HCV direct-acting antiviral (DAA) drugs, boceprevir and telaprevir, were not approved for co-infected patients. For novel DAA drugs, landscape is different: HIV/HCV patients have achieved similar sustained virologic response (SVR) rates as HCV monoinfected patients in clinical trials, but experience in safety and drug interactions with antiretroviral (ARV) regimens are limited, especially in cirrhotic patients.

Purpose

We evaluated the safety of DAA and ARV drugs in HCV patients co-infected with HIV-1 treated at the hospital from January to September 2015.

Materials and methods

HCV/HIV patients on stable ARV regimens were enrolled and received HCV-AAD treatments sofosbuvir/ledipasvir (SOF/LDV), ombitasvir/paritaprevir/ritonavir plus dasabuvir (OTV/PTV/r+DSV) and sofosbuvir plus daclatasvir (SOF+DCV), simeprevir (SOF+SMV) or ribavirine (SOF +RBV) for at least 4 weeks. Patients with compensated cirrhosis were eligible. All requests for HCV-treatments initiation were validated by a pharmacist with a checklist designed for it, considering drug interactions and adequacy recommendations. Safety evaluation was the primary endpoint and included frequency and severity of adverse event (AE) and standard laboratory parameter monitoring in addition to enhanced renal toxicity monitoring. CD4 count and HIV-1 RNA levels were measured to detect HIV virologic rebound.

Results

Socio-demographic and clinical characteristics

- 22 coinfected HIV-HVC patients
- 86% male; mean age was 51 (range 41-59)
- 86% had cirrhosis
- 86% treatment naïve
- 41% genotype (GT) 1a; 23% genotype (GT) 1b
- Others GT: GT2 (4%), GT3 (14%) and GT4 (23%)
- Mean baseline HCV RNA was 6.28 $\log_{10}$ IU/mL (range 5.9-7.0),
- Mean baseline CD4 count was 326 cells/uL (IQR=267)

- 68% complete 12-24 wks treatment duration and 32% are currently on treatment.
- 95% patients had undetectable HVC-viral load at week 4.
- One patient had confirmed HIV virologic rebound (HIV-1 RNA≥400 copies/mL), possibly related to DTG drug intolerance.
- No patients discontinued HCV treatment due to an AE.
- No significant laboratory abnormalities were observed.

Figure 1: Antiretrovirals regimens in co-infected patients treated with direct acting antivirals (%)

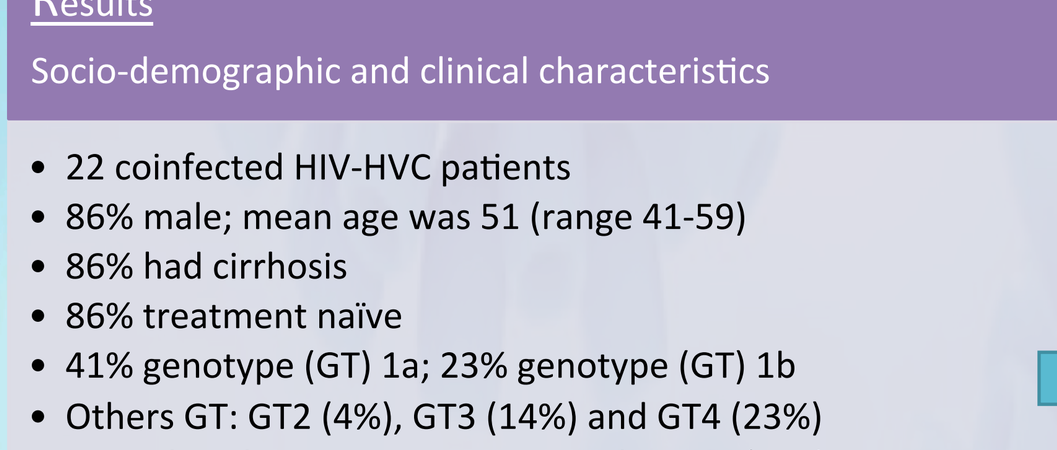
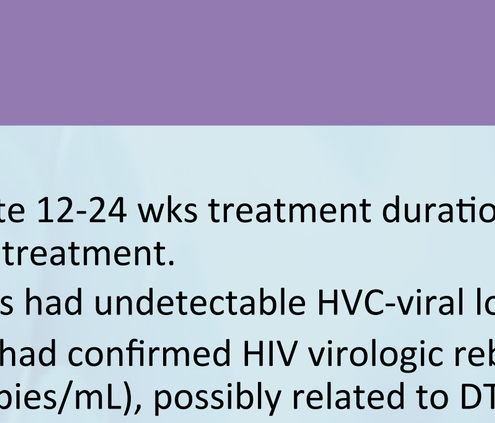


Figure 2: Adverse events in co-infected patients treated with direct acting antivirals



Conclusions

In our pilot study, oral HCV DAA drugs are safety and well tolerated in treatment-naïve and experienced, all genotype HCV-HIV patients, including those with cirrhosis. No patients discontinued treatment due to an AE and there were no significant clinical parameters abnormalities observed. This investigation line will continue because more patients are needed to confirm these results.

21st Congress of the EAHP, Viena 16-18th March 2016