Introduction and Objectives: Autoimmune liver disease (AILD) is one of the main causes of chronic liver disease (CLD). It comprises autoimmune hepatitis (AIH), primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), and immunoglobulin G4-associated cholangitis (IgG4-AC). Patients who exhibit features of two or more AILD are classified as overlap syndromes (OS); the most commonly seen is AIH/PBC. The aim of this study was to report trends of AILD in a liver unit (LU) over 26 years.

Material and Methods: Clinical records of patients who attended for the first time to LU, from January 1995 to December 2020 were included. There were 469 patients classified as AILD, and 462 were included, 408 (88%) females, mean age was 48 ± 14 (range. 4 - 78yo). Patients were divided into the three most common AILD: AIH, PBC, and OS. PSC and IgG4-AC were not included because they are very rare in our population. Diagnosis of AILD was made according to international guidelines, considering clinical manifestations, autoantibodies such as antinuclear antibodies (ANA), smooth muscle antibody (SMA), liver-kidney microsomal antibody (LKM), antimitochondrial antibodies (AMA), and when available: type 2 AMA, ANA gp210, liver biopsy, and non-invasive study of liver fibrosis. Inclusion criteria: patients with confirmed or suspected AILD in their first visit to the outpatient clinic. Diagnosis could be confirmed in subsequent visits. Other etiologies of CLD were excluded.

Results: Over 26 years, trends of AILD have increased at the expense of AIH mainly (figure). The distribution of AILD was: AIH 289, PBC 143, and OS 30. Half the patients had cirrhosis (48%) on admission (AIH 58%, PBC 41%, and OS 31%). We found no statistically significant difference between AILD groups in cases and percentage of cases, ($F(2,23) = 3.252$, $p = 0.057$) and ($F(2,23) = 0.996$, $p = 0.385$) respectively. Autoantibodies available on admission were 95% in AIH, 82.5% in PBC, and 93% in OS. In AIH patients, 95% had ANA and/or AML positivity (≤1:40), and 78% (≤1:80), 11% had LKM positive. In PBC patients, 80% were positive for AMA, and of these, 48% had AMA2 positive. OS patients had 68% ANA and 69% AMA positivity. (Figure 1).

Conclusions: The most common AILD seen in a period of 26 years was AIH; a high proportion of these patients had ANA and/or AML positive. Half of the PBC patients with AMA positive were also AMA2 positive. Two-thirds of OS patients exhibited ANA and AMA, confirming AIH/PBC. As in other CLD in Mexico, half the patients had cirrhosis on admission.

Funding: The resources used in this study were from the hospital without any additional financing

Declaration of interest: The authors declare no potential conflicts of interest.

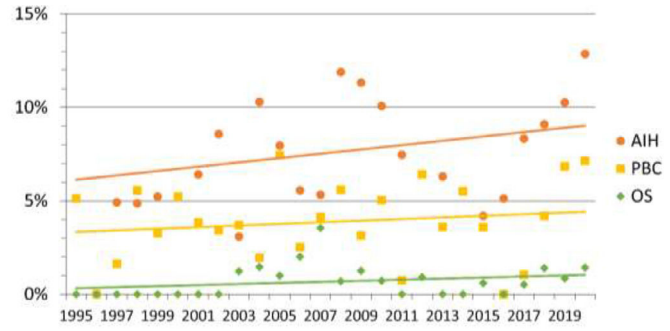

Figure 1. Trends gave in cases/year

https://doi.org/10.1016/j.aohep.2022.100823

Risk of multiple drug interactions potentially linked to safety in patients receiving pangenotypic direct-acting antivirals for the treatment of Hepatitis C

J Mendez-Navarro[1], J Turnes[2], A García-Herola[3], R Morillo[4], M Méndez[5], M Rueda[5], C Hernández[6], A Sicras-Mainar[7]

[1] *Medical Affairs. Gilead Sciences Mexico*
[2] *Gastroenterology and Hepatology Department. CHU. Pontevedra, Spain*
[3] *Digestive Medicine Department. Hospital Marina Baixa de Villajoyosa (Alicante), Spain*
[4] *Hospital Pharmacy. Hospital de Valme. AGS Sur de Sevilla. Spain*
[5] *Medical Affairs. Gilead Sciences S.L. Madrid, Spain*
[6] *Global Medical Affairs. Gilead Sciences Europe Ltd. U.K.*
[7] *Health Economics and Outcomes Research. Atrys Health. Barcelona, Spain*

Introduction and Objectives: Previous studies have evaluated the risk of drug-drug interactions (DDI) in HCV patients receiving pangenotypic direct-acting antivirals (pDAA), but all are based on pairwise interaction. The aim of the study was to describe the prevalence of the risk of potential multiple DDI (multi-DDI) and its clinical impact in patients treated with pDAAs.

Materials and Methods: Retrospective observational study from a Spanish database of 1.8 million inhabitants, including patients treated with Sofosbuvir/Velpatasvir [SOF/VEL] or Glecaprevir/Pibrentasvir [GLE/PIB] (2017- 2020). Demographics, comorbidities, comedications, and DDIs were evaluated for the pDAA therapy period. The severity and impact of the DDIs were evaluated using the University of Liverpool tool. Additionally, the ICD-9 coding system was used to identify the presence of suspected adverse drug reactions (SADR) during the treatment with pDAAs. An indirect indicator of effectiveness was evaluated (requirement of a new DAA in the six months after the end of the pDAA).

Results: 1620 patients were included; 730 with SOF/VEL (median age: 55 y; 62% men; 37.8% F3/4) and 890 with GLE/PIB (53 y; 60% men; 28% F3/4). The most prescribed drugs were nervous drugs (35.8%), digestive (24.1%) and cardiovascular (14.2%). 77.5% of patients received ≥2 comedications. The number of patients receiving ≥ 2 comedications at risk of multi-DDI with pDAAs was 123 (9.8%, 123/1256), 52 with SOF/VEL and 71 with GLE/PIB. Patients showing increased risk in comedication as a DDI outcomes were 31% (22) with GLE/PIB and 11% (6) with SOF/VEL ($p < 0.001$). The risk of decrease in pDAA with GLE/PIB was 32% (23) and with SOF/VEL 46% (24) (p=NS). Regarding SADR, there was a higher number in the GLE/PIB group (14) vs. SOF/VEL group (4) ($p<0.05$). 84% (16/18) of patients with SADR had a multi-DDI profile. 13% of total multi-DDIs patients showed SADR; GLE/PIB group showed SADR in 18% (13/71) vs. 6% (3/52) in SOF/VEL group ($p < 0.05$). Most SADR were reported with statin group, being the percentage higher in the GLE/PIB group vs. SOF/VEL group ($p < 0.05$).

Both pDAAs showed a similar percentage of patients restarting a new pDAA within the six months after the end of treatment (1.0% and 1.1%, respectively, p=NS).

Conclusions: In Spain, about 10% of HCV patients taking ≥ 2 comedications are at risk of multiple DDI with pDAAs. The potential risk of increased comedication as DDI outcome and the presence of suspected adverse reactions were higher in GLE/PIB in comparison with SOF/VEL.

Funding: The resources used in this study were from the hospital without any additional financing

Declaration of interest: The authors declare no potential conflicts of interest.

https://doi.org/10.1016/j.aohep.2022.100824