

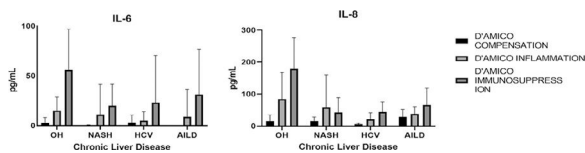
with HCV and AILD, increased serum levels of IL-8 and IL-6 were shown in decompensation stages (Figure 1).

**Discussion:** In this study, we demonstrated a significant increase in the pro-inflammatory cytokine profile in patients in the inflammation and immunosuppression phases. Fischer J et al. reported that a greater understanding of the mechanisms associated with immune dysfunction has led to the identification of possible therapeutic targets, with the intention of reducing the risk of infection and preventing decompensation events and disease progression.

**Conclusion:** This study demonstrated a significant increase in the pro-inflammatory cytokine profile (IL-8 and IL-6) as cirrhosis progresses. This is consistent with in the inflammation and immunosuppression phases, assessed by the Child-Pugh severity scales in stages B and C, D'amico from stages 3 to 5 and MELD> from 16 to 24 points and from 25 to 34 points. in the four etiologies included, being statistically significant.

The authors declare no conflict of interest.

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### CONNECTIVE TISSUE GROWTH FACTOR (CTGF) AS A PROMOTER IN THE DEVELOPMENT OF FIBROSIS IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS

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**Introduction and Objectives:** Primary biliary cholangitis (PBC), an immune-mediated disease, is characterized by destroying the intrahepatic bile ducts, leading to progressive damage to the biliary tree, cholestasis, and development of progressive fibrosis leading to cirrhosis with all its complications. The development of fibrosis is multifactorial and includes connective tissue growth factor (CTGF). In a mouse model of cholestasis by bile duct ligation, the hepatic and serum increase in CTGF associated with the progression of fibrosis was demonstrated. Our goal was to determine the relationship between CTGF levels and their association with the development of fibrosis in patients with PBC.

**Material and methods:** Prospective, cross-sectional, and analytical study, including patients with PBC. The degree of fibrosis was determined by transient elastography (Fibroscan). Serum concentrations of FCTC-8pg/ml were quantified, for statistical analysis, the SPSS version 25.0 software was used; the medians (Q3, Q1) of CTGF, alkaline phosphatase, gamma-glutamyl-transpeptidase, and degree of fibrosis were compared with the Mann-Whitney U test with significance less than 0.05.

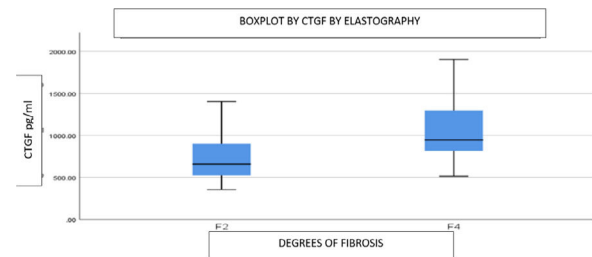
**Results:** We included 30 patients, 29 women (96.6%) and 1 man (3.4%), with a mean age of 55.5±12.4 years. Overexpression of CTGF protein was shown in 28 subjects (93.3%). Regarding the degree of fibrosis, all patients were categorized into one of two stages: Significant fibrosis (F2) and cirrhosis (F4). The F2 group had 11 patients with a median and standard deviation for CTGF of 915.9 and 522.9,

respectively; The F4 group had 19 patients who showed a median: 945.7 (1313.85-738.32); p:0.025. In relation to the differences between fibrosis levels and markers of alkaline phosphatase cholestasis, the median and interquartile ranges F2: 79 (180.60) F4: 169 (266-5.84) p: 0.066; GGT: F2: 1.51(7.7-1.04); F4: 1.2(2-1.92) p:0.746 In (Figure 1) The difference in medians of patients with different degrees of fibrosis and different concentration of CTGF is shown, confirming the association between peptide and the development and progression of fibrosis.

**Discussion:** According to the results obtained in patients with CBP and chronic cholestasis, the increase in CTGF showed significant differences between the degree of fibrosis and its levels; this could perhaps be interpreted as if it were an important factor for the development and progression of liver fibrosis, taking into account the antecedent of the initial study in mice with bile duct ligation and secondary cholestasis, where this factor was overexpressed at the hepatic and serum level in subjects with advanced fibrosis. It will be important to add more samples to this work and compare it with healthy controls to have better evidence.

**Conclusions:** Connective tissue growth factor (CTGF) probably participates directly in the processes of synthesis of extracellular matrix and therefore in the progression of fibrosis in subjects with primary biliary cholangitis, which makes it a possibility of a therapeutic target to develop in future studies.

The authors declare that there is no conflict of interest.



(Figure 1) The difference in medians of patients with different degrees of fibrosis and different concentration of CTGF is shown, confirming the association between peptide and the development and progression of fibrosis.

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### Global real-world evidence of sofosbuvir/velpatasvir (SOF/VEL) as a highly effective treatment in underserved patient populations because of mental health disorders, incarceration or homelessness

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**Introduction and Objectives:** The treatment of vulnerable populations must be prioritized to accomplish the WHO HCV elimination goals by 2030, including patients with mental health disorders, incarcerated patients or homeless patients. Simplifying the treatment cascade and rapid treatment start is key to achieving this goal, even more so in the COVID-19 era. Sofosbuvir/velpatasvir (SOF/VEL) is a protease inhibitor-free, pangenotypic, panfibrotic, single duration, single tablet regimen, to be taken without regards to food and with limited drug-drug interactions, allowing treatment simplification. Purpose: This real world data (RWD) analysis evaluates the effectiveness and safety of SOF/VEL for 12 weeks in a heterogeneous HCV population who suffer a mental health disorder, are incarcerated, or homeless.

**Materials and Methods:** 33 clinical cohorts across Australia, Canada, Europe & USA included 1,888 patients, 280 of them (from 6 clinical cohorts) were treated in Canada and overall managed following local standards of care. Adults were included if SOF/VEL for 12 weeks was started before November 2019 and completed while suffering a mental health disorder, being incarcerated or homeless, irrespective of genotype (GT), presence of compensated cirrhosis (CC) or treatment experience. Exclusion criteria were history of decompensation, prior NS5A-inhibitor exposure, treatment duration >12 weeks or addition of ribavirin. Sustained virological response (SVR;  $\geq 12$  weeks after end-of-treatment) and time to treatment initiation were assessed.

**Results:** Overall analysis includes 1,888 (71.3% male) patients (1,422 with a mental health disorder, 526 incarcerated, 153 homeless) aged 50 years, 24.4% were taking antipsychotic drugs and 52.2% of patients had former or current intravenous drug use. 43.2% patients had HCV GT1, 11.6% GT2, 36.3% GT3, 5.9% GT4-6, and 3.0% mixed/unknown GT. 19.0% patients had CC and 12.4% were treatment-experienced. In 257 patients (13.6%), SVR was not evaluated due to non-virological or unknown reasons; 79.9% of those were lost to follow-up (LTFU). When SVR was measured, 98.0% (n=1598/1631) achieved SVR, with 97.6%, 98.9% and 100% in patients with a mental health disorder, incarcerated or homeless patients, respectively. SVR was 98.5% in non-cirrhotic and 95.4% in CC patients. SVR remained >95% under antipsychotic use or coexistence of two negative factors of non-response such as GT3 plus active drug use or psychiatric disorder. SVR was similar, irrespective of time from diagnosis to treatment. Detailed analysis of the Canadian cohort data will be presented at the conference.

**Conclusion:** A test-and-treat strategy, easily implemented with SOF/VEL, and supported by the AASLD/ALEH/APASL/EASL joint call to action, could further enhance the population-level efficacy of HCV therapy by reducing the rate of non-virologic failure due to LTFU and related factors.

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