

has been related in parallel to the increase in the prevalence of obesity, insulin resistance (IR), type 2 diabetes (T2D) and other components of the metabolic syndrome (3).

Insulin resistance (IR) has been characterized as the main factor in the pathogenesis of NAFLD, and in turn, the presence of T2D is a predictor of advanced fibrosis and mortality (4). Insulin resistance assessments often require invasive and expensive methods, which has generated the search for indirect measures and precise RI. Currently, non-insulin based fasting IR indices have been developed, substituting insulin measurements for triglyceride measurements, fasting glucose and lipoproteins (5).

Recently, a novel surrogate index was developed to estimate the action of insulin without the determination of insulin. The metabolic score for insulin resistance (METS-IR) is calculated using fasting glucose, triglyceride, and HDLc measurements along with body mass index (BMI). METS-IR is an indirect method that correlates with fat intravisceral, intrahepatic and intrapancreatic and is useful for the prediction of T2D (5).

The identification of risk factors for NAFLD development and the availability of non-invasive tests for its diagnosis, offers a window of timely interventions that can modify the outcome of patients, improve the quality of life and reduce its impact on public health.

The primary objective in this work is to determine if there is a correlation between metabolic score for insulin resistance and the grade of hepatic steatosis in nonalcoholic fatty liver disease corroborated by elastography, in patients from Juarez Hospital of Mexico.

**Materials and Patients:** A retrospective, cross-sectional and analytical study was carried out. Patients aged 15 to 85 years were included, who had a diagnostic elastography and who had a diagnosis of NAFLD. Within the exclusion criteria, patients diagnosed with T2D who were under medical treatment, hepatitis B and C virus infection, history of autoimmune liver disease and history of chronic alcohol consumption, with a consumption greater than 30 g in men and 20 g in women, patients diagnosed with liver cirrhosis under medical treatment, patients with cholestatic syndrome and pregnant patients.

Descriptive statistics were performed with measures of central tendency and dispersion, inferential statistics using T student, and the correlations were determined with Pearson's correlation coefficient, being statistically significant  $P < 0.05$ .

**Results:** Elastographies with reports of fatty infiltrations and fibrosis and were gathered carried out between January 2017 and December 2018 in the Liver Clinic of the Gastroenterology service of the Juárez Hospital of Mexico. 283 elastography reports were obtained, of which, due to non-inclusion criteria, 207 were discarded, leaving a total of 76 patients for statistical analysis.

Within this population, 23.7% ( $n = 18$ ) were men and 76.3% ( $n = 58$ ) are women. According to the definitions of body mass index, the population was classified as normal weight, overweight and obesity. The population with normal BMI was 15.8% ( $n = 12$ ) of the population, overweight patients in 48.7% ( $n = 37$ ) and patients with obesity in 35.5% ( $n = 27$ ). The main number of patients was found in the overweight group, being higher in the group of women, with 48.3% ( $n = 28$ ).

A correlation was made between the METS-IR with the degree of fat infiltration and liver fibrosis, and a correlation of fat infiltration with body mass index. Correlation was obtained between the METS-IR index with the degree of fatty infiltration with statistical significance ( $p = 0.029$ ) in general and a correlation with any METS-IR index value and the different degrees of hepatic steatosis in particular.

**Conclusions:** The METS-IR index is a novel method for determining insulin resistance in patients with metabolic risk factors. This is

the first study to evaluate the relationship of the METS-IR index with NAFLD, and the correlation between IR and hepatic fat infiltration was verified. The higher the value of METS-IR, the greater the presence of fat infiltration. We consider the METS-IR as a valuable screening tool for liver disease in a population whose access to invasive diagnostic studies is limited.

#### Ethical statement

The protocol was registered and approved by the Ethics Committee. The identity of the patients is protected. Consentment was obtained.

#### Declaration of interests

None

#### Funding

None

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#### Prolonged-release pirfenidone in patients with compensated cirrhosis. Final results of the multicenter study ODISEA, controlled against placebo, plus standardized care\_2023

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**Introduction and Objectives:** Advanced liver fibrosis (ALF) is a predictor of adverse prognosis in chronic liver disease. In addition to etiological treatment, a new approach to stop or reverse residual fibrosis would be desirable. Our aim was to assess the efficacy and safety of a prolonged-release pirfenidone formulation (PR-PFD) compared to placebo, plus standardized care, in patients with compensated liver cirrhosis.

**Materials and Patients:** 180 patients with ALF (F4 by elastography) of various causes were randomly assigned to 3 groups: placebo (G1), PR-PFD: 1200 mg/d (G2) or 1800 mg/d (G3), plus standardized care, during 24 months. All participants underwent standard lab tests, quality of life assessment, elastography, fibrotest, liver US, and endoscopy at baseline and at 12 and 24 months. Ethics Committee Registry H14-004. Patients signed an informed consent, which will be in custody for 15 years. This study was funded by CellPharma Laboratory.

**Results:** 165 patients were eligible for the efficacy and 180 for the safety analysis. At baseline, demographics, etiology, stage of cirrhosis, Child-Pugh or MELD scores, quality of life or fatigue scales, and liver stiffness (kPa) and Fibrotest (units) scores (mean ± 1SE) were similar between groups (multivariate mixed model). The estimated fibrosis scores presented a significant reduction, mainly in G2 (Table). Decompensations were detected in 19 patients: variceal bleeding (5), encephalopathy (4), hepatocarcinoma (4) with similar distribution between groups. Ascites (12) was more frequent in the placebo group (p=0.003). G2 patients presented significant improvements between baseline and 24 months in: ALT (43.5 ± 3.8 vs. 31.3 ± 4.8 UI/L, p=0.003), albumin (4.2 ± 0.06 vs. 4.5 ± 0.07 g/dL, p<0.001); total bilirubin (0.90 ± 0.08 vs. 0.65 ± 0.10 mg/dL, p<0.001); platelets (121.7 ± 7.8 vs. 144.3 ± 9.7 × 10<sup>3</sup>/μL, p<0.001), MELD (9.73 ± 0.32 vs. 9.03 ± 0.40, p=0.022) and quality of life (83.7 ± 1.5 vs. 90.9 ± 1.9 %, p=0.002). Adverse events were mainly mild from the GI tract (n=48, 46, and 35) and skin (n=15, 22, and 12) in G1, G2, and G3, respectively.

**Conclusions:** Prolonged-release pirfenidone at a dose of 1200 mg significantly decreased indirect fibrosis markers at 24 months and

induced improvement in LFTs, MELD, and quality of life in compensated cirrhosis and without safety concerns.

**Ethical statement**

HI14-004

**Declaration of interests**

None

**Funding**

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**Table.**

The estimated fibrosis scores presented a significant reduction, mainly in G2

Elastography kPa	Group 1 (Placebo)	Group 2 (1200 mg)	Group 3 (1800 mg)	Fibrotest (units)	Group 1 (Placebo)	Group 2 (1200 mg)	Group 3 (1800 mg)
Basal	27.5 ±2.3	24.2 ±2.3	24.4 ±2.3	Basal	0.86 ±0.02	0.86 ±0.02	0.87 ±0.02
24 mo	24.6 ±2.4	15.4 ±12.3	23.3 ±2.3	24 mo	0.84 ±0.02	0.82 ±0.02	0.84 ±0.02
P-value	0.402	0.001	0.654	P-value	0.101	0.001	0.045

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