23rd Latin American Congress for the Study of the Liver
ALEH
Cancún | México
September 11-13, 2014
www.aleh2014.com | Aleh2014@kenes.com

# NON-INVASIVE LIPIDOMICS TEST FOR IMPROVING ASSESSMENT OF NAFLD: CLINICAL PATIENTS DIAGNOSIS AND FOLLOW-UP

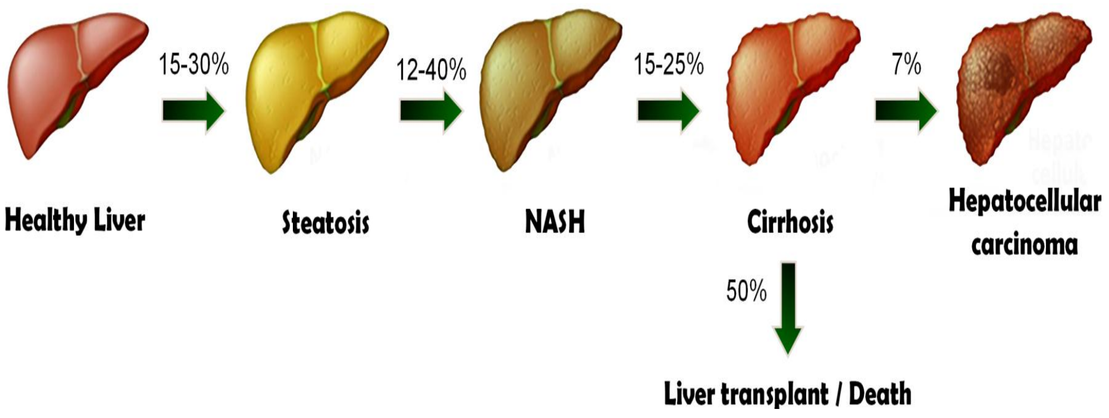
owl Diagnostics

**N.M. Irazabal-Remuiñan [1], L.F. Eraña-Ledesma [1], P. Salvador [2], S. Blanco [3], F. Menéndez [3], P. Ruiz [4], R. González-Monasterio [4], E. Delgado [5], J.I. Arenas [6], M. Martos [6], A. Otegui [7], G. Arregi [7], M.C. Eizmendi [7], S. Urquiola [7], T. Porto [8], A. Castro [8], J Bustamante [2], J.I. Pijoán [9]**

1 . Unidad de Gastroenterología, Hospital Universitario de Araba (Santiago), Vitoria-Gasteiz, Spain. 2 . Unidad de Gastroenterología y Hepatología, Hospital Universitario Cruces, BioCruces Health Research Institute, Barakaldo, Spain. 3 . Unidad de Gastroenterología, Hospital Universitario Basurto, Bilbao, Spain 4 . Unidad de Gastroenterología, Hospital San Eloy, Barakaldo, Spain. 5 . Unidad de Gastroenterología, Hospital Universitario de Araba (Txagorritxu), Vitoria-Gasteiz, Spain. 6 . Unidad de Gastroenterología, Hospital Universitario Donostia, Donostia-San Sebastián, Spain 7 . Centro de Salud de Zumarraga, Zumarraga, Spain. 8 . OWL, Derio, Spain. 9 . Unidad de Epidemiología Clínica y Soporte Metodológico, Hospital Universitario Cruces, BioCruces Health Research Institute, Barakaldo, Spain.

## 1 Background and aims

The spectrum of non-alcoholic fatty liver disease (NAFLD) ranges from hepatic steatosis to non-alcoholic steatohepatitis (NASH). Developing non-invasive approaches such as a BMI-dependent lipidomic signature test could represent a diagnostic milestone. We evaluated the performance of the Owl Liver Test (OLT) to differentiate liver steatosis from NASH and determine its relation to BMI, clinical parameters and other supporting medical exams.



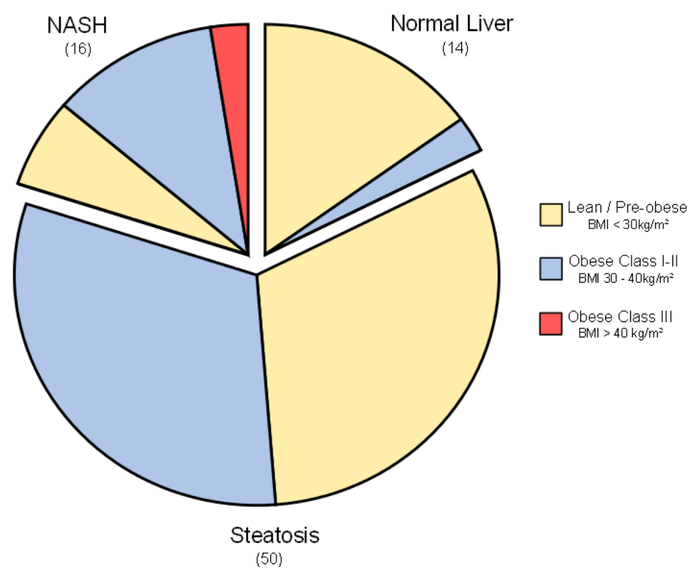

## 2 Methods

Eighty patients with NAFLD were recruited from 7 hospitals and 1 primary care centre of the Basque Public Health System. Blood samples were taken in two separate visits in 9 months time. In first visit, patients were prescribed diet and exercise. Serum metabolic profile was performed by a LC/MS-based platform that allows the semiquantitative analysis of 44 lipids. Clinical parameters and additional data were used to calculate NAFLD Fibrosis Score and the Clinical Model of Palekar.

**Clinical characteristics of patients**

| | N | Age (yrs) | Female Sex (%) | BMI (Kg/m²) | AST (U/liter) | ALT (U/liter) | Total Fasting Cholesterol (mg/dl) | Fasting Triglycerides (mg/dl) | Ferritine (ng/mL) | Fasting Glucose (mg/dl) |
|---|---|---|---|---|---|---|---|---|---|---|
| **Lean / Pre-obese Cohort** (BMI <30 kg/m²) | 42 | 47.3±9.3 | 40 | 26.3±2.3 | 40.4±20.4 | 65.8±28.7 | 223.±47.4 | 124.5±52.2 | 230.2±222.1 | 95.9±22.7 |
| **Obese Class I-II Cohort** (BMI 30-40 kg/m²) | 36 | 51.6±11.3 | 67 | 33.5±2.8 | 37.9±25.3 | 66.5±57.7 | 217.7±37.5 | 164.9±71.0 | 249.3 ±237.1 | 115.9±30.8 |
| **Obese Class III Cohort** (BMI >40 kg/m²) | 2 | 53.5±2.1 | 100 | 46.3±8.2 | 64.±46.7 | 72.±45.3 | 241.5±54.4 | 175.5±40.3 | 49.5±21.9 | 145.5±41.7 |

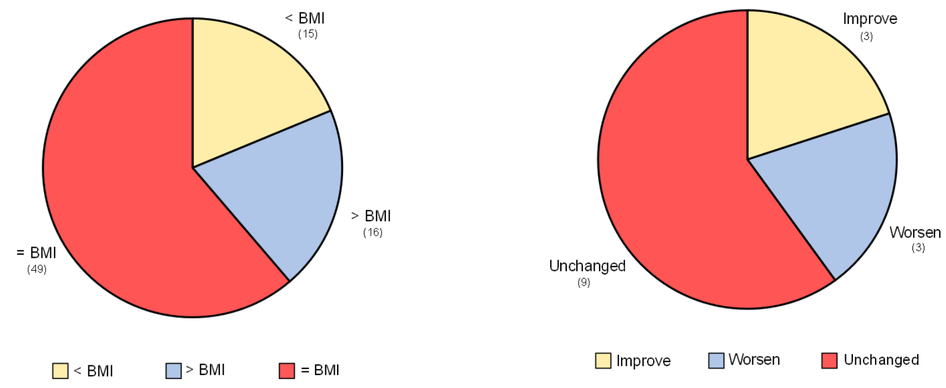
## 3 Results




**Baseline OLT Diagnostics**

OLT staging was stable in patients with minor changes in BMI over time but discrepancies were found in 3 cases: BMI decreased or remained unchanged in one case, although OLT diagnosis of NASH persisted or developed on follow-up; in another patient BMI increased slightly, but OLT results changed from NASH to steatosis; and in the last case a significant BMI reduction did not modify OLT diagnosis of NASH.

In all, test results were consistent with patient involvement in the control of the disease, concerning diet and exercise, for the 9 months of monitoring. They were also in accordance with biochemical and anthropometric determinations.




**a)** **b)**

**BMI after 9 months follow-up: a)** 49/80 patients kept a constant BMI during the 9 months, 16 increased this index and 15 decreased it; **b)** In patients in whom BMI decreased OLT staging remained unchanged in 9 cases (60%), improved in 3 (20%) and got worse in 3 (20%).

Furthermore, a small group (4 cases) of lean NAFLD patients (BMI <25) was identified. In these patients it was found that the test is less accurate in diagnosing NASH, so these patients with specific characteristics should be object of a closer monitoring as they fall out of the common NAFLD patients profile.

## 4 Conclusions

NAFLD is considered to become one of the most prevailing diseases of the 21th century in developed countries. Therefore, the development of a useful and non-invasive tool for NAFLD management is a matter of immediate concern.

The non-invasive OLT test seems to potentially meet these requirements as it may discriminate between different stages of the disease. It might also become a valuable approach to monitor progression of patients.