Stephen A Harrison – GENFIT SA: Consulting

Michael H. Trauner – Albireo, BiomX, Falk, Genfit, Gilead, Intercept, MSD, Novartis. Phenex. Regulus: Consulting; Albireo, Cymabay, Falk, Gilead, Intercept, MSD, Takeda: Grant/Research Support; Falk, Gilead, Intercept, MSD, Roche: Speaking and Teaching

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NON-INVASIVE SERUM LIPIDOMIC APPROACH TO DISCRIMINATE NON-ALCOHOLIC STEATOHEPATITIS IN MULTIETHNIC PATIENTS WITH TYPE 2 DIABETES MELLITUS

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Background: The OWLiver Test has been reported to be a good test for the diagnosis of Non-alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH) based on the triglyceride profile and Body Mass Index (BMI). However, this test is limited by the discovery population composed by Caucasians without type 2 diabetes mellitus (T2DM). The aim of this study was to refine the OWLiver Test considering other populations with different ethnicities and diabetic status. **Methods:** A multiethnic, multicenter discovery cohort of 616 adult subjects with biopsy proven NAFLD (263 Steatosis, 353 NASH) was analyzed. A logistic regression model was developed including lipidomic features and clinical variables and following a K-fold Cross-Validation process. Finally, the model was validated in a new independent blind cohort (n = 65; 18 Steatosis, 47 NASH). The diagnostic performance was reflected in area under the receiver-operating characteristic (AUROC) curve, sensitivity and specificity. Values are given as mean ±1 standard deviation of the mean. **Results:** The characteristics of the discovery cohort (n = 616) were 53% male, BMI (34.5 ± 6.44, kg/m^2), alanine aminotransferase (ALT = 53.33 ± 38.27, U/L), aspartate aminotransferase (AST = 38.63 ± 24.75, U/L) and glycated hemoglobin (HbA1c = 6.58 ± 1.17, %). The 24% of the cohort had a poor glycaemic control HbA1c > 7%. A novel lipidomic-based algorithm in serum was generated from this international multiethnic cohort of patients with type 2 diabetes, resulting in an AUROC of 0.79 ± 0.012 in training and 0.81 ± 0.047 in the K-fold Cross-Validation process. The sensitivity was 0.67 ± 0.012 (training) and 0.67 ± 0.049 (validation), and specificity was 0.77 ± 0.007 (training) and 0.80 ± 0.029 (validation). Previous version of the OWLiver test in this cohort got an AUROC < 0.7. An independent cohort from Chile was analyzed (n = 65): 29% male, BMI (31.21 ± 4.60, kg/m^2), ALT (81.96 ± 67.24, U/L), AST (55.60 ± 40.30, U/L) and HbA1c (6.13 ± 1.07, %). The new test was blindly evaluated in this cohort. The AUROC was 0.81 ± 0.064, sensitivity 0.72 ± 0.147 and specificity 0.72 ± 0.113, improving the results of previous version of the test that obtained a suboptimal performance. **Conclusion:** This new non-invasive test improves the results of the OWLiver test for the discrimination between steatosis and NASH in a more general population, taking into account the multiethnicity and diabetes status.

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Pablo Ortiz – OWL Metabolomics: Employment

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OBETICHOLIC ACID (OCA) IMPROVES NON-INVASIVE MARKERS OF FIBROSIS IN PATIENTS WITH NON-ALCOHOLIC STEATOHEPATITIS (NASH): A SECONDARY ANALYSIS OF THE PHASE 3 REGENERATE STUDY

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