

144 New Automated Evaluation Tool qFIBS - Quantitative Assessment for Fibrosis, Inflammation, Ballooning, and Steatosis in Patients with Non-Alcoholic Steatohepatitis

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Background: Nonalcoholic steatohepatitis (NASH) is a common cause of chronic liver disease worldwide and one of the leading underlying etiologies for liver transplantation. Currently clinical trials in NASH use the NASH Clinical Research Network (CRN) system for semiquantitative histological assessment to evaluate treatment efficacy. Interobserver variability may hamper histological assessment and clear diagnostic consensus among pathologists is not feasible in some cases. The aim of this study was to evaluate a novel second harmonic generation / two photon excitation fluorescence (SHG/TPEF) imaging-based tool (qFIBS) for the comprehensive and quantitative assessment of histological features (**F**ibrosis, **I**nflammation, **B**allooning of hepatocytes, **S**teatosis).

Methods: Images were acquired by SHG/TPEF from 329 NASH liver biopsy samples from Asia and Europe. These were used to develop and test qFIBS: computational algorithm that quantifies NAFLD Activity Score (NAS) components and fibrosis stage (qSteatosis, qBallooning, qInflammation and qFibrosis), relative to the NASH CRN scoring system (Fig. 1). Results: qFIBS showed good correlation with NASH CRN scoring ($P < 0.001$) - qFibrosis ($r = 0.721$), qInflammation ($r = 0.609$), qBallooning ($r = 0.586$) and qSteatosis ($r = 0.879$) - and high AUROC values - qFibrosis (0.830-0.925) ($P < 0.001$), qInflammation (0.819-0.848) ($P < 0.001$), qBallooning (0.816-0.818) ($P < 0.001$) and qSteatosis (0.932 - 0.970) ($P < 0.001$).

Conclusion: Our data demonstrates that qFIBS is a reliable tool for NASH biopsy evaluation and offers the potential to standardize histological analysis. The method accurately reflects the NASH CRN scoring for fibrosis, inflammation, ballooning and steatosis and as such, qFIBS potentially offers a relatively simple tool with which to standardize efficacy of intervention assessment in clinical trials.

Disclosures:

Dina Tiniakos – Intercept Pharmaceuticals, Inc: Consulting; HistoIndex Pte Ltd: Grant/Research Support; Safeblood Bionalytica SA: Grant/Research Support; Biodynamics SA: Grant/Research Support Manuel Romero-Gomez – Gilead: Grant/Research Support; Gilead: Advisory Committee or Review Panel; Intercept: Grant/Research Support; Intercept: Advisory Committee or Review Panel; Gilead: Speaking and Teaching; Genfit: Speaking and Teaching; Novo-Nordisk: Speaking and Teaching; Novo-Nordisk: Advisory Committee or Review Panel; Medimmune: Advisory Committee or R Elisabetta Bugianesi – GILEAD: Advisory Committee or

Review Panel; Intercept: Advisory Committee or Review Panel; Genfit: Advisory Committee or Review Panel
Stephen A. Harrison – Madrigal: Consulting; Madrigal: Stock Shareholder; Genfit: Consulting; Cirius: Consulting;
Genfit: Stock Shareholder; Cirius: Stock Shareholder; Metacrine: Consulting; NGM Bio: Consulting; Metacrine:
Stock Shareholder; Echosens: Consulting; Perspectum: Consulting; HistolIndex: Consulting; Prometheus:
Consulting; Corcept: Consulting; CiVi: C Quentin M. Anstee – Abbvie, Allergan/Tobira, Astra Zenica,
GlaxoSmithKline, Novartis Pharma AG, Pfizer Ltd., Vertex: Grant/Research Support; Abbvie, Antaros Medical*,
Allergan/Tobira, AstraZenica, Boehringer Ingelheim International GMBH*, Ellegaard Gottingen Minipigs AS*, Eli
Lilly & Company Ltd.*, Exalenz Bioscience Ltd.*, Genfit SA*, GlaxoSmithKline, Interc

The following people have nothing to disclose: Feng Liu, Aileen Wee, Jingmin Zhao, Huiying Rao, Xiao-Xiao
Wang, Qin Wang, Salvatore Petta, Chee-Kiat Tan, Jason Chang, Lai Wei Disclosure information not available
at the time of publication: Boon Bee George Goh, Leow Wei-Qiang, Wei-Keat Wan, Kiat Hon Lim.

Abstract Credits: HEPATOLOGY, VOLUME 68, NUMBER 1 (SUPPL) AASLD ABSTRACTS (Oral)