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.

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