

Non-Alcoholic Fatty Liver Disease / Non-Alcoholic Steato-Hepatitis Biomarkers: Are we stuck with biopsies? Diagnostic Tools beyond Biopsies

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Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steato-hepatitis (NASH) are disease modalities of increasing prevalence and therefore relevance for health care systems. NAFLD is the most common cause of chronic liver disease (CLD) in the United States where it affects 80-100 million Americans of whom 10%-22% may have nonalcoholic steatohepatitis (NASH). NAFLD/NASH prevalence rates in other geographies are similar, with reported peaks of >50% in some geographies. NASH as the progressive form of the disease may lead to cirrhosis and hepatocellular carcinoma.

NAFLD is associated with obesity, insulin resistance, hypertension, diabetes, and dyslipidemia. Currently the diagnostic gold standard to diagnose advanced fibrosis is liver biopsy, however in looking at the increasing incidence and prevalence of

NAFLD/NASH it is quite obvious that liver biopsies aren't a suitable tool to diagnose or to monitor progression of a disease as prevalent as NAFLD/NASH.

While stringent regulatory guidance on acceptable biomarkers beyond biopsies, that are suitable for disease staging, assessment of disease progression or monitoring of therapeutic interventions are missing, there has been remarkable progress in developing diagnostic tools both imaging biomarkers and circulating biomarkers, that may have the potential to become acceptable surrogates and that may even replace liver biopsies in the future.

This review will present recent developments in liver imaging (e.g. MRI-PDFF, MRS-PDFF, MRE) and in identifying specific metabolites (e.g. lipid metabolites like poly-unsaturated fatty acids) indicative of progression of NAFLD / NASH.