Novel Fibroscan-Based Score to Diagnose NASH and its severity in A Multi-centre UK Cohort of Patients with Suspected NAFLD

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Background & Aims: Reliable non-invasive biomarkers are needed for the diagnosis and monitoring of patients with non-alcoholic steatohepatitis (NASH). Our study set out to determine the performance of a new score developed by Echosens to

differentiate NASH and simple steatosis based on a single Fibroscan examination (liver stiffness and controlled attenuation parameter (CAP)).

Methods: Patients with suspected NAFLD prospectively underwent FibroScan examination within 2 weeks of a standard of care liver biopsy (LB) between March 2014 and January 2016 at seven UK centers. LB were read in a blinded manner by two expert pathologists. NASH was diagnosed using the FLIP algorithm. NASH severity was graded according to the NAS score. To develop a score to diagnose NASH the cohort was split randomly into training (80%) and validation (20%) sets. Sample splitting was repeated 100 times leading to the selection of the optimum model. This was tested on an external validation cohort that consisted of 47 NAFLD patients from a single liver centre in France. Patients there underwent FibroScan examination within 1 day of LB, read by the same pathologists.

Results: 174 patients with BMI <40 kg/m^2 were studied. The following patients were excluded for the score development: LB not interpretable/diagnostic of NAFLD (n=18), FibroScan not possible (n=1), FibroScan unreliable according to Boursier's criteria (n=10). Patients had a median BMI of 32.9 [IQR=6.9] kg/m2 and age of 54 [21] years. 58% were male, 74% had a NAS score ≥3 and 58% had NASH. The external validation cohort had a median BMI of 30.0 [8.0] kg/m2 and age of 53 [22] years. 67% were male, 82% had a NAS score ≥3 and 71% had NASH, 91% had a reliable Fibroscan examination. Performance of the scores is shown in the table.

Conclusion: A novel score based on measurement of liver stiffness and CAP from a single FibroScan examination was able to correctly classify 79% of patients with/without NASH as well as correctly staging severity in 86%. This has promise as a non-invasive marker for detecting/staging disease activity in patients with NASH.