Staging fibrosis and excluding advanced fibrosis in patients with NAFLD: comparison of non-invasive markers in an interim analysis from a prospective multicenter study

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Background & Aims: Hepatic fibrosis is a major determinant of clinical outcomes in non-alcoholic fatty liver disease (NAFLD) and there remains a clear need to establish the accuracy of non-invasive markers of fibrosis. This study aims to prospectively compare the diagnostic performance and ability to exclude advanced fibrosis of the

following non-invasive tests in NAFLD: FibroScan, FibroMeter V, FibroMeter NAFLD, FibroMeter VCTE, NAFLD Fibrosis score (NFS), Fib4, APRI, BARD and AST/ALT ratio.

Methods: Patients with suspected NAFLD prospectively underwent FibroScan examination and blood sampling within 2 weeks of a standard of care liver biopsy (LB) between March 2014 and January 2016 at seven UK centres. LB were staged in a blinded manner by two expert pathologists according to the NASH CRN system. Diagnostic performance was assessed in terms of area under the ROC curves (AUC). Ability to exclude advanced fibrosis was assessed using published cut-offs except for FibroMeter (FM), for which cut-offs have not yet been published. Cut-offs for FM were determined that maximized the Youden index.

Results: 155 patients (57% male, median age 54 [IQR 20] years, median BMI 33.2 [8.1] kg/m2) had a complete dataset for analysis. Fibrosis distribution was: F0: 23%, F1: 25%, F2: 21%, F3: 25%, F4: 6%. 43% of the patients had a NAS score ≥5. Performance summary of the tests is presented below in the table.

Conclusion: FibroMeter VCTE, which combines biochemical parameters with liver stiffness measured by FibroScan, has the highest performance characteristics with positive and negative predictive values of 67 and 93% respectively at confirming or excluding ≥F3 fibrosis.