Non-Invasive Detection of Fibrotic NASH in NAFLD Patients with Low or Intermediate FIB-4

Info

PUBLISHED DATE
2022-08-01

JOURNAL
Journal of Clinical Medicine

LINK
https://doi.org/10.3390/jcm11154394

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Abstract

Background: Non-alcoholic steatohepatitis (NASH) and fibrosis are the main prognostic factors in non-alcoholic fatty liver disease (NAFLD). The FIB-4 score has been suggested as an initial test for the exclusion of progressed fibrosis. However, increasing evidence suggests that also NASH patients with earlier fibrosis stages are at risk of disease progression, emphasizing the need for improved non-invasive risk stratification. Methods: We evaluated whether the apoptosis biomarker M30 can identify patients with fibrotic NASH despite low or intermediate FIB-4 values. Serum M30 levels were assessed by ELISA, and FIB-4 was calculated in an exploration (n = 103) and validation (n = 100) cohort of patients with histologically confirmed NAFLD. Results: The majority of patients with low FIB-4 (cut-off value < 1.3) in the exploration cohort revealed increased M30 levels (>200 U/L) and more than 80% of them had NASH, mostly with fibrosis. NASH was also detected in all patients with intermediate FIB-4 (1.3 to 2.67) and elevated M30, from which ~80% showed fibrosis. Importantly, in the absence of elevated M30, most patients with FIB-4 < 1.3 and NASH showed also no fibrosis. Similar results were obtained in the validation cohort. Conclusions: The combination of FIB-4 with M30 enables a more reliable identification of patients at risk for progressed NAFLD and might, therefore, improve patient stratification.