Screening for therapeutic trials and treatment indication in clinical practice: MACK-3, a new blood test for the diagnosis of fibrotic NASH.

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Résumé en anglais	BACKGROUND: The composite histological endpoint comprising nonalcoholic steatohepatitis (NASH) and NAFLD activity score ≥4 and advanced fibrosis (F ≥ 2) ("fibrotic NASH") is becoming an important diagnostic target in NAFLD: it is currently used to select patients for inclusion in phase III therapeutic trials and will ultimately be used to indicate treatment in clinical practice once the new drugs are approved. AIM: To develop a new blood test specifically dedicated for this new diagnostic target of interest. METHODS: Eight Hundred and forty-six biopsy-proven NAFLD patients from three centres (Angers, Nice, Antwerp) were randomised into derivation and validation sets. RESULTS: The blood fibrosis tests BARD, NFS and FIB4 had poor accuracy for fibrotic NASH with respective AUROC: 0.566 ± 0.023, 0.654 ± 0.023, 0.732 ± 0.021. In the derivation set, fibrotic NASH was independently predicted by AST, HOMA and CK18; all three were combined in the new blood test MACK-3 (hoMa, Ast, CK18) for which 90% sensitivity and 95% specificity cut-offs were calculated. In the validation set, MACK-3 had a significantly higher AUROC (0.847 ± 0.030, P ≤ 0.002) than blood fibrosis tests. Using liver biopsy in the grey zone between the two cut-offs (36.0% of the patients), MACK-3 provided excellent accuracy for the diagnosis of fibrotic NASH with 93.3% well-classified patients, sensitivity: 90.0%, specificity: 94.2%, positive predictive value: 81.8% and negative predictive value: 97.0%. CONCLUSION: The new blood test MACK-3 accurately diagnoses fibrotic NASH. This new test will facilitate patient screening and inclusion in NAFLD therapeutic trials and will enable the identification of patients who will benefit from the treatments once approved.
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