



# Development and Validation of Hepamet Fibrosis Scoring System-a Simple, Non-invasive Test to Identify Patients With Nonalcoholic Fatty liver Disease With Advanced Fibrosis

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**BACKGROUND & AIMS:** Fibrosis affects prognoses for patients with nonalcoholic fatty liver disease (NAFLD). Several non-invasive scoring systems have aimed to identify patients at risk for advanced fibrosis, but inconclusive results and variations in features of patients (diabetes, obesity and older age) reduce their diagnostic accuracy. We sought to develop a scoring system based on serum markers to identify patients with NAFLD at risk for advanced fibrosis.

**METHODS:** We collected data from 2452 patients with NAFLD at medical centers in Italy, France, Cuba, and China. We developed the Hepamet fibrosis scoring system using demographic, anthropometric, and laboratory test data, collected at time of liver biopsy, from a training cohort of patients from Spain (n=768) and validated the system using patients from Cuba (n=344), Italy (n=288), France (n=830), and China (n=232). Hepamet fibrosis score (HFS) were compared with those of previously developed fibrosis scoring systems (the NAFLD fibrosis score [NFS] and FIB-4). The diagnostic accuracy of the Hepamet fibrosis scoring system was assessed based on area under the receiver operating characteristic (AUROC) curve, sensitivity, specificity, diagnostic odds ratio, and positive and negative predictive values and likelihood ratios.

Résumé en anglais

**RESULTS:** Variables used to determine HFS were patient sex, age, homeostatic model assessment score, presence of diabetes, levels of aspartate aminotransferase, and albumin, and platelet counts; these were independently associated with advanced fibrosis. HFS discriminated between patients with and without advanced fibrosis with an AUROC curve value of 0.85 whereas NFS or FIB-4 did so with AUROC values of 0.80 (P=.0001). In the validation set, cut-off HFS of 0.12 and 0.47 identified patients with and without advanced fibrosis with 97.2% specificity, 74% sensitivity, a 92% negative predictive value, a 76.3% positive predictive value, a 13.22 positive likelihood ratio, and a 0.31 negative likelihood ratio. HFS were not affected by patient age, body mass index, hypertransaminasemia, or diabetes. The Hepamet fibrosis scoring system had the greatest net benefit in identifying patients who should undergo liver biopsy analysis and led to significant improvements in reclassification, reducing the number of patients with undetermined results to 20% from 30% for the FIB-4 and NFS systems (P<.05).

**CONCLUSIONS:** Using clinical and laboratory data from patients with NAFLD, we developed and validated the Hepamet fibrosis scoring system, which identified patients with advanced fibrosis with greater accuracy than the FIB-4 and NFS systems. the Hepamet system provides a greater net benefit for the decision-making process to identify patients who should undergo liver biopsy analysis.

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