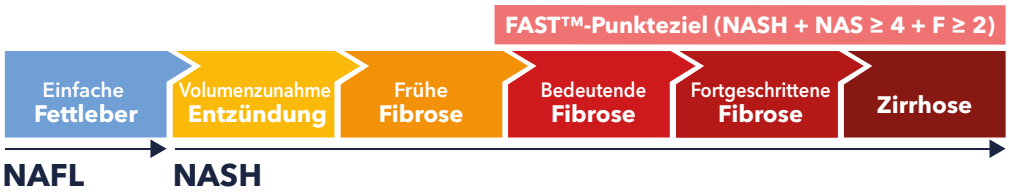
Scores
by echosens

Fast™

Identifizierung von NASH-Risikopatienten

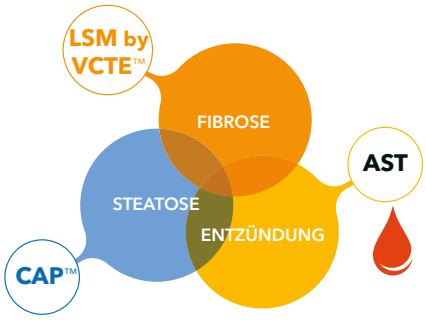
Die Belastung durch nicht-alkoholische Fettlebererkrankungen (NAFLD) nimmt weltweit zu. Einer der wichtigsten Schwerpunkte liegt auf der Identifizierung von Patienten mit nicht-alkoholischer Steatohepatitis (NASH), die ein höheres Risiko für das Fortschreiten bis zur Zirrhose haben sowie Kandidaten für klinische Studien und neue Pharmakotherapien sein können.

Zielgruppe



Funktionsweise

FibroScan® by echosens



Leistungsfähigkeit

- **Gute bis hervorragende Ergebnisse in der Derivationskohorte sowie in externen Validierungskohorten aus verschiedenen klinischen Settings (Einrichtungen der NAFLD-Tertiärversorgung, Screening, Adipositaschirurgie) und mit verschiedener geographischen Herkunft (USA, Europa, Asien)**

Die Formel ist öffentlich mit einem kostenlosen Rechner in der myFibroScan-App erhältlich.

myFibroScan

GET IT ON Google Play Download on the App Store

Kostenlose App

Referenzen:

- Newsome P.N. *et al.*, FibroScan-AST (FAST) score for the non-invasive identification of patients with non-alcoholic steatohepatitis with significant activity and fibrosis: a prospective derivation and global validation study. Lancet Gastroenterology & Hepatology 2020
- Anand *et al.*, FibroScan-AST score in an Asian cohort of NAFLD and its utility in predicting histological resolution with bariatric surgery. J Gastroenterol Hepatol 2020
- Blank *et al.*, Current NAFLD guidelines for risk stratification in diabetic patients have poor diagnostic discrimination. Sci Rep 2020
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- Puri *et al.*, Use of FibroScan-AST Score to Stratify High-Risk Nonalcoholic Steatohepatitis in US Veterans. Clinical gastroenterology and Hepatology 2020
- Noureddin *et al.*, Driving Nonalcoholic Steatohepatitis Forward Using the FibroScan Aspartate Aminotransferase Score. Hepatology 2020
- Oeda, S. *et al.*, Diagnostic accuracy of FibroScan-AST score to identify non-alcoholic steatohepatitis with significant activity and fibrosis in Japanese patients with non-alcoholic fatty liver disease: Comparison between M and XL probes. Hepatol Res, 2020
- Oh *et al.*, Weight-loss-independent benefits of exercise on liver steatosis and stiffness in Japanese men with NAFLD. JHEP Reports, 2021

LSM: Lebersteifigkeitsmessung /AST: Aspartataminotransferase

CE

Veröffentlichung (Lancet Gastroenterol Hepatol 2020)

FibroScan-AST (FAST) score for the non-invasive identification of patients with non-alcoholic steatohepatitis with significant activity and fibrosis: a prospective derivation and global validation study

P.N. Newsome, M. Sasso, J.J. Deeks, A. Paredes, J. Boursier, W.K. Chan, Y. Yilmaz, S. Czernichow, M.H. Zheng, V.W. Wong, M. Allison, E. Tsochatzis, Q.M. Anstee, D.A. Sheridan, P.J. Eddowes, I.N. Guha, J.F. Cobbold, V. Paradis, P. Bedossa, V . Miette, C. Fournier-Poizat, L. Sandrin, S.A. Harrison

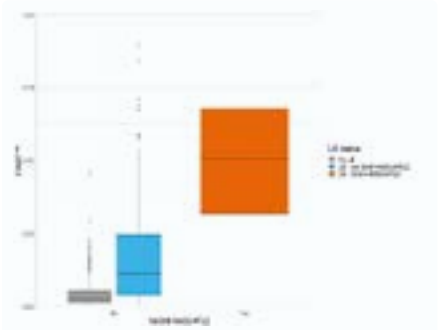
	Derivation cohort (UK NAFLD)	French bariatric surgery cohort	USA screening cohort	China Hong-Kong NAFLD cohort	China Wenzhou NAFLD cohort	French NAFLD cohort	Malaysian NAFLD cohort	Turkish NAFLD cohort	Pooled external cohort
N Patients	**350**	**110**	**242**	**83**	**104**	**182**	**176**	**129**	**1026**
AUROC [95% CI]	0.80	0.95	0.86	0.85	0.84	0.80	0.85	0.74	0.85
Rule out cut-off	**≤0.35**								
% patients	**32%**	**63%**	**80%**	**34%**	**53%**	**37%**	**44%**	**20%**	**51%**
Se/Sp	0.90/0.53	1/0.73	0.64/0.86	0.94/0.55	0.89/0.56	0.88/0.56	0.94/0.54	0.91/0.35	0.89/0.64
NPV	0.85	1	0.95	0.93	0.98	0.87	0.97	0.73	0.94
Indeterminate	**0.35 - 0.67**								
% patients	**39%**	**20%**	**16%**	**35%**	**36%**	**38%**	**34%**	**44%**	**30%**
Rule in cut-off	**≥0.67**								
% patients	**29%**	**17%**	**4%**	**31%**	**11%**	**24%**	**22%**	**36%**	**19%**
Se/Sp	0.90/0.48	0.93/0.75	0.99/0.25	0.89/0.58	0.92/0.44	0.89/0.45	0.87/0.58	0.82/0.49	0.92/0.49
PPV	0.83	0.63	0.78	0.81	0.33	0.76	0.54	0.78	0.69

Se Sensitivität / Sp Spezifität / NPV negativer Vorhersagewert / PPV positiver Vorhersagewert

ILC 2019

A FibroScan-based score : FAST™, combining liver stiffness, controlled attenuation parameter and AST can efficiently screen for presence of at risk fibrotic NASH

S.Harrison, J. Whitehead, V. Paradis, P. Bedossa , A. Paredes



BACKGROUND & AIMS: Given the increased need to identify NASH patients with fibrosis in drug development, Echosens has developed a score to identify patients with NASH+NAS≥4+F≥2. The score combined the FibroScan liver stiffness measurement (LSM), controlled attenuation parameter (CAP) and AST. The objective was to assess its performance in a cohort of patients screened for NAFLD.

METHODS: Patients were screened for NAFLD in one American center. Patients with MRI-PDFF≥5% or liver inflammation and fibrosis score (LIF)≥2 or FibroScan LSM≥7kPa or MRE LSM≥3kPa were advised to undergo a liver biopsy (LB). The performance of the score was assessed using area under the receiver operating characteristics (AUC).

RESULTS: 510 patients were included in the analysis: 240 with LB and 270 with no LB (all 4 liver imaging modalities "normal" (below the predefined cutoffs)). 50% of were female, median age was 56 [IQR=10] years and BMI was 30.3 [7.3] kg/m2. At LB, 37 (15%) patients had at F≥2, 91 (38%) had NASH and 27 (11%) had a NASH+NAS≥4+F≥2. Of note, 7 (3%) had F≥2 but no NASH and 3 (1%) had NASH, F≥2 and NAS≥4. Cutoffs value for a sensitivity (Se) and specificity (Sp) ≥0.90 and associated diagnostic metrics are provided in Table 1. AUC for the score to detect NASH+NAS≥4+F≥2 was 0.88 (0.81-0.94) and significantly outperforming FibroScan LSM (0.77 (0.68-0.86), p=0.006), CAP (0.71 (0.63-0.80), p<10-3) and AST (0.76 (0.66-0.86), p=0.004) alone. Using the lower cutoff, 97 patients (19% of the population) would have been sent for referral. Among those patients, 26% were NASH+NAS≥4+F≥2, 69% weren't and 5% had normal imaging modalities. Using the higher cutoff, 38 patients (7% of the population) would have been sent for referral. Among those patients 42% were NASH+NAS≥4+F≥2, 55% weren't and 3% had normal imaging modalities. With the hypothesis that patients with normal imaging were not NASH+NAS≥4+F≥2, prevalence of NASH+NAS≥4+F≥2would drop to 5%. Corresponding positive and negative value (PPV/NPV) of the score would be 0.26/99.5 for the lower cutoff and 0.42/97.7 for the higher cutoff.

CONCLUSION: A simple score based on FibroScan LSM, CAP and AST can be used to efficiently identify patients eligible for potential pharmacologic therapy.

ILC 2020

Validation of FibroScan®-asparate aminotransferase based score to detect at risk non-alcoholic steatohepatitis in a large North American non-alcoholic fatty liver disease cohort.

M. Lazo, M.L. Van Natta, A. Sanyal, J. Tonascia, N. Chalasani, S. Gawrieh, S. Siddiqui, C. Behling S. Dasarathy, A.M. Diehl, K.V. Kowdley, R. Loomba, A. McCullough, N. Terrault, B. Tetri and Raj Vuppalanchi

BACKGROUND & AIMS: An unmet need for management of patients with nonalcoholic fatty liver disease (NAFLD) is an accurate non-invasive tool to identify the NAFLD patients who have "at risk" nonalcoholic steatohepatitis (NASH) – the type of NASH puts patients at risk for progression to cirrhosis. The FAST (FibroScan®-aspartate aminotransferase [AST]) score was recently developed and validated in 7 external cohorts (n=1026) and showed moderate diagnostic accuracy for "at risk" NASH (AUROC=0.85). Our aims were to: (1) evaluate the diagnostic accuracy of the FAST score in a large North American NAFLD cohort, the NIH/NIDDK's NASH Clinical Research Network (NASH CRN) and (2) to determine whether the FAST diagnostic accuracy differs by patient subgroups or FibroScan® exam features.

METHODS: We conducted a cross-sectional study in 585 adults with biopsy-confirmed NAFLD. We defined "at risk NASH", as patients with NASH who had a NAFLD Activity Score (NAS) ≥4 and a fibrosis stage ≥2, as determined using the NASH CRN's centrally-graded histology panel. We calculated FAST score using liver stiffness (E kPa), steatosis (controlled attenuation parameter [CAP] dB/m), and AST (U/L) in the formula provided by Echosens; we also used the provided FAST-based "Rule-Out" (sensitivity = 90%) and "Rule-In" (specificity =90%) zones defined by FAST cut-points = 0.35 and 0.67 respectively. The primary measure of accuracy was area-under-the-Receiver-Operating-Characteristic (AUROC). We also calculated sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for the cut-points above in the NASH CRN cohort. We repeated the above for subgroups of patients defined by gender, age, race, obesity, diabetes and dyslipidemia status, FibroScan® exam probe, and quality criteria.

RESULTS: Our sample of 585 adults was 38% male, 79% white, 14% Hispanic, and had mean (range) age = 51 (18-77) yrs, ALT = 66 (13-351) U/L, and AST = 50 (11-368) U/L, 73% with obesity). A total of 214 (37%) had "at risk" NASH. The AUROC for the FAST score for "at risk" NASH was 0.81 (95% CI: 0.77, 0.84). Using the "rule out at-risk NASH" cut-off, the sensitivity, specificity, PPV and NPV were 0.91, 0.50, 0.51 and 0.90, respectively. Using the "rule in at-risk NASH" cut-off, the sensitivity, specificity, PPV and NPV were 0.51, 0.87, 0.69 and 0.76, respectively. The performance of the FAST score was higher in non-whites vs. whites (AUROC: 0.91 vs 0.78; p=0.0002) and inversely related to obesity status (AUROC: 0.94 in normal, 0.84 in overweight, and 0.78 in both obese and morbid obese; p=0.04). No differences were observed by other patient demographics, co-morbidities, size of probe or unreliability of measurement.

CONCLUSION: We validated moderate accuracy of Fibroscan®-based FAST score for diagnosing "at risk" NASH, in a large, multi-racial population from North America. Future studies are needed to further examine the usefulness of the FAST score or its variants to track changes in histological outcomes over time.