Scores
by echosens

Fast™

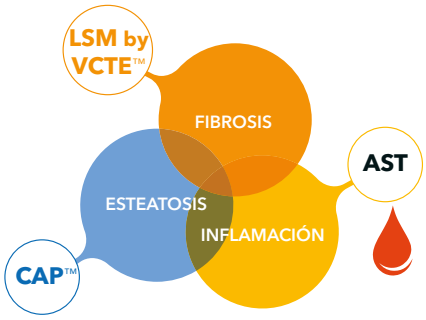
Identificación de pacientes con NASH en riesgo

La enfermedad del hígado graso no alcohólico (NAFLD) es un problema cada vez mayor a nivel mundial. Una de las principales prioridades es identificar a los pacientes con esteatohepatitis no alcohólica (NASH) que presentan un mayor riesgo de progresión a cirrosis y que serían candidatos para ensayos clínicos y nuevas farmacoterapias emergentes.

Objetivo

Funcionamiento

FibroScan® by echosens



Rendimiento

- **Rendimiento bueno o excelente en la cohorte de derivación, así como en cohortes de validación externas de diferentes contextos clínicos (unidad de atención terciaria de la NAFLD, cribado, cirugía bariátrica) y orígenes geográficos (EE. UU., Europa, Asia)**

La fórmula es pública con una calculadora gratuita disponible en la aplicación myFibroScan

myFibroScan

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Aplicación gratuita

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LSM: Medición de elasticidad del hígado / AST: Aspartato-aminotransferasa

CE

Publicación (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

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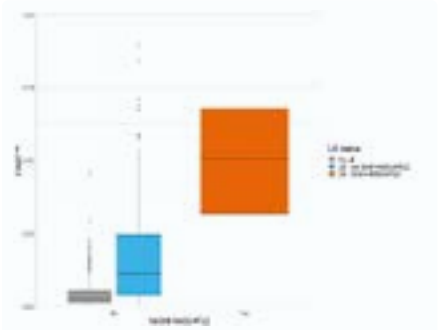
	Derivation cohort (UK NAFLD)	French bariatric surgery cohort	USA screening cohort	China Hong-Kong NAFLD cohort	China Wenzhou NAFLD cohort	French NAFLD cohort	Malaysian NAFLD cohort	Turkish NAFLD cohort	Pooled external cohort
N Patients	**350**	**110**	**242**	**83**	**104**	**182**	**176**	**129**	**1026**
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: sensibilidad / Sp: especificidad / NPV: valor predictivo negativo / PPV: valor predictivo positivo

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.

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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.