

RECOMMENDED CLINICAL CARE PATHWAY (CCP) WITH FIB-4 UNDERESTIMATES THE PREVALENCE OF ADVANCED FIBROSIS (AF) COMPARED TO SEQUENTIAL CCP WITH LIVERFAST GP+ (LIVERSTAT) AND LIVER STIFFNESS MEASUREMENT (LSM) BY FIBROSCAN



Naim Alkhouri ¹, Ronald Quiambao², Mona Munteanu² | 1. Arizona Liver Health, Phoenix, AZ, USA. 2. Medical Affairs Department Fibronostics US Inc, Florida, USA

BACKGROUND		AIM	RESULT											
Clinical care pathways (CCPs) have been developed to assist clinicians, in diagnosing NAFLD with advanced fibrosis (AF) using The study aims to assess comparatively, on the 2017-			Study flowchart		Strength of concordance between LSM (Fibroscan) and LiverSTAT for the detection of advanced fibrosis									
noninvasive sequential testing with FIB-4 followed by liver stiffness March 202		Varch 2020 pre-pandemic	NHANES cohort		OVERKALL COHORT					SUBGROUP WITH TYPE2 DIABETES				
measurement (LSM) by Fibroscan and other proprietary algorithms. Kanwal, Gastroenterology 2021; Rinella, Hepatology 2023 fil		NHANES cohort, the prevalence of advanced fibrosis (AF) using recommended sequential FIB-4 and LSM and using the	2017-March -202 pre-pandemic N=15,560	20	LiverSTAT	No presumed fibrosis (Class AB)	Presumed fibrosis, no advanced fibrosis	Presumed advanced fibrosis	Total	LiverSTAT	No presumed fibrosis (Class AB)	Presumed fibrosis, no advanced fibrosis	Presumed advanced fibrosis	Total
 LiverSTAT (formerly LIVERFASt GP+) is a noninvasive blood-based Al- triage test combining common biochemistry with anthropometrics for detecting NAFLD-related fibrosis and steatosis. 			(i c apj	Excluded Incomplete data or not plicable LSM by TE)	LSM <8kPa	4940	1429	337	6709	LSM <8kPa	344	341	106	791
 LiverSTAT outperforms FIB-4, without limitations related to age or diabetes. 		newly released triage tool, iverSTAT, downstream of			LSM ≥8KPa	244	308	183 (2.5%)	732	LSM ≥8KPa	\42	115	93 (8.9%)	250
de Lédinghen, JHepatol 2023-A		iver stiffness measurement LSM) with vibration		N=8,119	Total	5194	1737	520	7441	Total	386	456	199	1041
We recently validated LiverSTAT for detecting NAFLD advanced fibrosis (AF) with 100% histological confirmation along with elastography (VCTE) by			Included subject liver assessmen with LSM, FIB-4 a	ts nt nnd	Presur	Presumed AF with LSM and LiverSTAT according to FIB-4 group, overall population Presumed AF with LSM and LiverSTAT a to FIB-4 group, population with type 2							STAT accord sype 2 diabe	ding etes
Alkhouri, JHepatol 2023-A			N=7,441	Presumed AF with FIB-4 >2.67 227 (3.1% from the		th :he :	Grey zone FIB-4 1.3 to 2.67 1765 (23.7% from the overall cohort)		Presumed AF with FIB-4 >2.67 52 (5% from the T2DMcohort)		FIB- 381 (3	Grey zone FIB-4 1.3 to 2.67 381 (36.6% from the T2DM cohort)		
				laracteristics of included patients		verall cohort)			T2
 We extracted data (N= 15,560 subjects) from National Health and Nutrition Examination Survey (NHANES) 2017-March -2020 pre- pandemic LiverSTAT: Subjects were assigned to one of the four diagnostic classes: Class D defines the presumed advanced fibrosis (AF). EIB-4: Cut-offs of 2 68 and 1 3 have been used for to 			N=7,441	Mean (se) or prevalences (%)	Presu	Presumed AF fibrosis Presumed		Presumed AF fil	prosis	Presumed AF fibrosis		Presu	Presumed AF fibrosis	
			Age (median), years Gender, males	49 (0.2) 47.4%	86/227 (1.16%))	226/1765 (3%)		28/52 (2.7%)		94/	94/381 (19.1%)	
			Type 2 Diabetes ("Doctor told they have diabetes")	1041 (14%)	Pres with L 5	esumed AF fibrosis Prr h LiverSTAT (Class D) with 57/86 (0.77%)		Presumed AF fibrosis vith LiverSTAT (Class D) 85/226 (1.14%)		Presumed AF fibrosis with LiverSTAT (Class D) 23//28 (2.2%)		Presu with Liv 42	Presumed AF fibrosis with LiverSTAT (Class D) 42/94 (4.0%)	
 Selected subjects aged 18 years or more assign subjects to AF category and to the 			BMI Kg/m2	29.6 (0.1)										
without missing data for FIB-4, LiverSTAT and LSM with applicable transient elastography (TE) were included (see below description of the			2010, 19, 112 2010 (012)											
			ALT, IU/L AST. IU/L	T, IU/L 22.6 (0.2) ST. IU/L 22.6 (0.2)			CONCLUSION							
methods)	LSM, Fibroscan, Kpa CAP, db/m	5.8 (0.06) 263 (1)	• In LS	 In NHANES pre-pandemic cohort, using the strength of concordance betw LSM by Fibroscan and LiverSTAT instead of FIB-4, the prevalence of presi 							nce betw of presur	veen med		
The agreement between methods to identify AF have been estimated using recommend CCP (FIR-4 and					advanced fibrosis was estimated as being twice higher than (2.5% vs. 1.2%									
LSM) and LiverS	fibrosis prevalences • LiverSTAT	520 (7.0%)	respectively).											
VCTE by Fibroscan (Echosens, Paris, France) • Quality criteria: IQR/median<30%,	LIVERSTAT (Fibronostics, Florida, US Al computer aided proprietary algorithm for	US) $\begin{array}{c} FIB-4 \ Index \\ Algorithm: platelet count, age, AST and ALT \\ RIB-4 = {age(vgar) \times AXT(UU/L)} \\ RIB-4 = {age(vgar) \times AXT(UU/L)} \\ \hline Dual cut-off for advanced fibrosis (<1.45, >3.25) \\ Over or underestimation: age range, cytosis, normal ALT and AST (T2D) \\ Lower of underestimation: age ronge, in T2D \\ \end{array}$	 FIB-4 (> 2.67) LSM, Fibroscan 	227 (3.1%) 595 (8.0%)	• Among subjects with type 2 diabetes, the prevalence of presumed AF was 8.9%									
Success rate260%, 10 valid LSM • Variability in 531 NAFLD patients paired measurements: one stage	assessing fibrosis and steatosis Combines seven blood biomarkers and anthropometrics to generate a category of		FIB-4 Indeterminate zone (IZ) (1.3-2.67)	1765(23.7%)	• LiverSTAT can be used as a triage tool, along with confirmatory LSM, to better									
difference in 32%, two stages difference in 10% • Overestimation: Cytolysis with ALT	fibrosis/steatosis Can be used in fasting or non-fasting patients		TE Non-Applicable (NA)		identify subjects for hepatologist referral									
> 3x ULN, non fasting, MetS: T2D, BMI>30, high-blood pressure Castera, Hepatology 2010, Nascimbeni, CGH 2014	Image: Control of the contro				Disclosures: RQ, MM: Fibronostics US Inc. Slides are the property of the author and AASLD. Permission is required from both AASLD and the author for re-									

