LIVERSTAT for the diagnosis of compensated advanced chronic liver disease in patients with type 2 diabetes

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ABSTRACT

Introduction: LIVERSTAT is a non-invasive artificial intelligence-based test that provides risk stratification for metabolic dysfunction-associated steatotic liver disease. We aimed to study the performance of LIVERSTAT compared with the Fibrosis-4 Index (FIB-4) as a stand-alone test and as a first-line test to identify patients for liver stiffness measurement (LSM) for the diagnosis of compensated advanced chronic liver disease (cACLD) in patients with type 2 diabetes (T2D).

Materials and Methods: This is a cross-sectional study of patients with T2D who underwent transient elastography. cACLD was defined as LSM ≥10 kPa. As a stand-alone test, LIVERSTAT Class D and increased FIB-4 ≥1.3 (≥2.0 if age ≥65 years old) were considered as having cACLD. As a first-line test, LIVERSTAT Class D and increased FIB-4 were considered as requiring LSM.

Results: We analysed data for 221 patients (mean age 61 years, 41% male, cACLD 26%). The area under the receiver operating characteristic curve, sensitivity, specificity, positive predictive value, negative predictive value and misclassification rate for LIVERSTAT were 0.66, 32%, 88%, 47%, 79% and 27%, respectively. The corresponding values for FIB-4 were 0.61, 39%, 81%, 41%, 79%, and 30%, respectively. When using LIVERSTAT as a first-line test, the proportion of patients requiring LSM was 17% (38/221), while the proportion of false negatives was 19% (34/183). The corresponding values for FIB-4 were 24% (54/221) and 19% (31/167), respectively.

Conclusion: LIVERSTAT has similar accuracy as FIB-4 when used as a stand-alone test or as a first-line test to identify patients for LSM for the diagnosis of cACLD in patients with T2D.

KEYWORDS:
Metabolic dysfunction-associated steatotic liver disease, MASLD, cACLD, Fibrosis-4 Index, fibrosis

INTRODUCTION

Metabolic dysfunction-associated steatotic liver disease (MASLD) is the most common cause of chronic liver disease, affecting an estimated 38% of the general population.[1] The prevalence of MASLD is even higher among patients with type 2 diabetes (T2D) and was found to be 50-72% in previous studies in our centre.[2-3] Moreover, T2D is an independent factor associated with more severe MASLD, and a substantial proportion of patients with T2D have more severe liver disease.[3-4] Therefore, patients with T2D represent an important target group for identifying patients with more severe MASLD.[5]

The term compensated advanced chronic liver disease (cACLD) was introduced to reflect the continuum of advanced fibrosis and cirrhosis in asymptomatic patients who are at risk of developing clinically significant portal hypertension (CSPH).[6] A pragmatic definition of cACLD based on liver stiffness measurement (LSM) was introduced with the aim to stratify the risk of CSPH and decompensation at the point of care, irrespective of the histological stage or the ability of LSM to identify these stages.[6]

The Fibrosis-4 index (FIB-4) is one of the most widely used biomarkers of liver fibrosis and has been recommended for the evaluation of fibrosis in patients with MASLD.[7–13] LIVERSTAT (Fibronostics, Indian Harbour Beach, FL, United States) is an artificial intelligence-based test incorporating anthropometric measurements and blood biomarkers for screening and risk stratification for MASLD.[14] Similar to FIB-4, LIVERSTAT uses readily available parameters, but it may be better than FIB-4. In a previous study, we found LIVERSTAT to have a higher negative predictive value compared with FIB-4 and a lower misclassification rate compared with FIB-4 when used in a two-step approach in combination with LSM for the diagnosis of advanced liver fibrosis.[14] We hypothesized that LIVERSTAT may be better, or at least as good as FIB-4, when used in patients with T2D. Therefore, we conducted this study with the objectives of assessing LIVERSTAT as a stand-alone diagnostic tool for cACLD and as a first-line test to identify patients for further evaluation using LSM to diagnose cACLD, compared with FIB-4, in patients with T2D.

MATERIALS AND METHODS

This study utilised previously collected, anonymised data from patients with T2D who had undergone transient elastography in a cross-sectional study. The study was conducted to determine the prevalence of non-alcoholic fatty

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liver disease and its more severe form among patients with T2D and enrolled consecutive adult patients (aged ≥18 years) who were seen by a senior endocrinologist at the Diabetes Clinic, Universiti Malaya Medical Centre, Kuala Lumpur, Malaysia between December 2016 and December 2017.[2] Demographic, anthropometric, clinical, and laboratory data were recorded using a standard protocol. Patients with incomplete data for the calculation of FIB-4 and/or LIVERSTAT were excluded from the study. The study conformed to the ethical guidelines of the 1975 Declaration of Helsinki, and ethical approval was obtained from our institutional review board (MREC ID No.: 20159-1650). All patients who participated in the study provided written informed consent.

Transient elastography

All patients underwent vibration-controlled transient elastography using FibroScan (Echosens, Paris, France). The examination was performed after overnight fasting by an experienced operator (LLL) using either M probe or XL probe based on the device recommendation. The examination was considered reliable if there were 10 valid acquisitions with an inter-quartile range over median of ≤ 30% for LSM.[15] We used LSM ≥10 kPa to define cACLD in accordance with the Baveno VII consensus and local guidelines.[5,6,12,13] Patients with controlled attenuation parameter (CAP) ≥263 dB/m were considered as having significant hepatic steatosis.[2,16]

LIVERSTAT

The LIVERSTAT result for each patient in this study was generated using the online platform by Fibronostics (https://portal.fibronostics.com/) using de-identified anthropometric and laboratory data and blinded to LSM data. LIVERSTAT uses a proprietary algorithm incorporating eleven variables, namely age, weight, height, gender, triglycerides, total cholesterol, fasting glucose, total bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT) and gamma glutamyl transferase to categorise patients into four diagnostic categories. The diagnostic categories were based on a quantitative normalised score (0.00-1.00) for fibrosis assessment and a binary assessment for steatosis. The diagnostic categories were Class A (no presumed fibrosis and no presumed steatosis >5%), Class B (no presumed fibrosis but presumed steatosis >5%), Class C (presumed mild or moderate fibrosis without bridging), and Class D (presumed severe fibrosis with bridging). For this study, patients with LIVERSTAT Class D were considered as having cACLD, and patients with LIVERSTAT Class A were considered as not having significant hepatic steatosis, while patients with LIVERSTAT Class B were considered as having significant hepatic steatosis.

FIB-4

FIB-4 was calculated using the formula: age (years) * AST / [platelet (x10^9/L) * square root (ALT)]. For this study, patients with a FIB-4 score ≥1.3 (≥2 if age ≥65 years old) were considered as having cACLD.

Statistical analyses

Statistical analyses were performed using IBM SPSS Statistics 27.0 (IBM, Armonk, NY, USA) and R.[17] Data was expressed as absolute values and percentages for categorical variables and analysed using the Chi-square test or Fisher's exact test, where appropriate. Continuous variables were expressed as mean with standard deviation or median with interquartile range and analysed with Student's t-test or the Mann-Whitney U test, where appropriate. The accuracy of LIVERSTAT and FIB-4 for the diagnosis of cACLD was assessed using the area under the receiver operating characteristic curve (AUROC). AUROCs were interpreted as follows: 0.90-1.00 = excellent, 0.80-0.90 = good, 0.70-0.80 = fair, <0.70 = poor. The sensitivity, specificity, positive predictive value, negative predictive value and misclassification rate were determined. The accuracy of LIVERSTAT for the diagnosis of cACLD was compared with that of FIB-4 using DeLong's test. Significance was assumed if p was <0.05. Calibration of predicted probabilities against observed risk was evaluated using bootstrap-corrected calibration curves (500 resamples). We assessed the clinical utility of LIVERSTAT and FIB-4 using decision-curve analysis to compare net benefit across clinically relevant threshold probabilities. In the analysis to compare LIVERSTAT with FIB-4 as a first-line test to identify patients for further evaluation using LSM, patients with LIVERSTAT Class D, and patients with FIB-4 ≥1.3 (≥ 2.0 if age ≥65 years old), were considered as requiring further evaluation using LSM. The proportion of patients requiring further evaluation using LSM (i.e., the referral rate) and the false negative rate when using LIVERSTAT and FIB-4 as a first-line test to identify patients for further evaluation using LSM were determined.

RESULTS

Patient characteristics

The data for 221 patients were included in the final analysis for this study. A total of 336 patients from the original research project were excluded from this study due to missing data to calculate LIVERSTAT and/or FIB-4, mainly AST and platelet count. The patient characteristics are presented in Table I. The mean age of the study population was 60.8 ± 11.3 years, and 41% were male. The majority of patients were obese (75%) and centrally obese (81%). Significant hepatic steatosis was found in 82% of patients, while cACLD was found in 25.8%. Patients with cACLD were more likely to have central obesity and had higher weight, body mass index and waist circumference. They had significantly higher serum triglyceride, alanine aminotransferase, aspartate aminotransferase and gamma glutamyl transferase levels, and lower high-density lipoprotein cholesterol and platelet count.

LIVERSTAT and FIB-4 for the diagnosis of cACLD

The receiver operating characteristic curve of LIVERSTAT and FIB-4 for the diagnosis of cACLD is shown in Figure 1. LIVERSTAT had an AUROC of 0.66 (95% CI, 0.58-0.74), while FIB-4 had an AUROC of 0.61 (95% CI, 0.52-0.70), for the diagnosis of cACLD (p = 0.27). The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of LIVERSTAT for the diagnosis of cACLD were 32% (95% CI, 19% - 45%), 88% (95% CI, 82% - 92%), 47% (95% CI, 34% - 61%), 79% (95% CI, 75% - 82%) and 73% (95% CI, 67% - 79%), respectively. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy of FIB-4 for the diagnosis of cACLD were 39% (95% CI, 26% - 52%), 80% (95% CI, 74% - 86%), 41% (95% CI, 30% - 52%), 79% (95% CI, 75% - 82%) and 70% (95% CI, 63% - 76%),

Table I: Patient characteristics of the study (N=221)

Variables	Overall population, N=221	Patients with cACLD, n=57	Patients without cACLD, n=164	p-value
Age, years	60.8±11.3	60.6±10.3	60.9±11.7	0.86
Male, n (%)	91 (41)	27 (47)	64 (39)	0.27
Weight, kg	72.9±15.2	77.2±15.9	71.4±14.7	0.02
Height, m	1.60±0.09	1.60±0.1	1.60±0.09	0.83
BMI, kg/m^2	28.4±5.2	29.9±4.6	27.9±5.3	0.012
Obesity, n (%)	165 (75)	49 (86)	117 (71)	0.054
Waist circumference, cm	95.6±13.1	100.7±13.6	93.8±12.4	0.001
Central obesity, n (%)	180 (81)	52 (91)	128 (80)	0.045
SBP, mmHg	138±19	135±17	139±19	0.15
DBP, mmHg	77±11	76±11	78±11	0.43
FBS, mmol/L	8.6 (6.30-9.7)	9.0 (6.7-10.4)	8.5 (6.2-9.5)	0.205
Triglyceride, mmol/L (IQR)	1.7 (0.6-6.9)	1.9 (0.7-4.6)	1.7 (1-2)	0.016
TC, mmol/L	4.4 (1.5-8.2)	4.3 (2.6-8.2)	4.4 (3.6-5.1)	0.269
HDL cholesterol, mmol/L	1.3±0.4	1.2±0.3	1.3±0.4	0.014
LDL cholesterol, mmol/L	2.3 (1.7-2.8)	2.3 (1.6-2.8)	1.8 (1.8-2.8)	0.21
ALT, U/L	33 (17-39)	42 (23-48)	30 (17-37)	<0.001
AST, U/L	30 (19-32)	37 (21-47)	28 (18-29)	0.001
GGT, U/L	59 (21-55)	104 (29-113)	44 (20-43)	<0.001
Albumin, g/L	41.7±4.6	41.5±3.7	41.8±4.9	0.85
Bilirubin, μmol/L	11 (7-13)	11 (7-13)	11 (8-13)	0.67
Platelet count x10^9/L	282 (227-334)	259 (201-305)	290 (235-344)	0.015

cACLD, compensated advanced chronic liver disease; BMI, body mass index; SBP, systolic blood pressure; DBP, diastolic blood pressure; FBS, fasting blood sugar; TC, total cholesterol; HDL, high-density lipoprotein; LDL, low-density lipoprotein; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma glutamyl transferase

Table II: The status of compensated advanced chronic liver disease and significant hepatic steatosis according to LIVERSTAT and Fibrosis-4 index categories

Indexes/Tests	Categories	cACLD*	No cACLD*	Significant hepatic steatosis**	No significant hepatic steatosis**
LIVERSTAT categories	Class A	2	33	23	12
	Class B	12	46	54	4
	Class C	25	65	74	16
	Class D	18	20	31	7
LIVERSTAT***	Positive	18	20	31	7
	Negative	39	144	151	32
FIB-4 categories	<1.3 (age <65) or <2 (age ≥65)	35	132	140	27
	≥1.3 (age <65) or ≥2 (age ≥65)	22	32	42	12
FIB-4****	Positive	22	32	42	12
	Negative	35	132	140	27

*cACLD based on liver stiffness measurement ≥10 kPa
**Significant hepatic steatosis based on controlled attenuation parameter ≥263 dB/m
***LIVERSTAT Class D was considered as positive for cACLD,
****FIB-4 ≥1.3 (age <65) or ≥2 (age ≥65) was considered as positive for cACLD
cACLD, compensated advanced chronic liver disease

respectively. The cACLD status according to LIVERSTAT and FIB-4 categories is shown in Table II.

Calibration plots for LIVERSTAT and FIB-4 for the diagnosis of cACLD is shown in Figure 2. LIVERSTAT demonstrated good agreement between predicted and observed risk for cACLD (mean absolute error 0.03). FIB-4 showed moderate calibration, with slight underestimation of risk at higher predicted probabilities (mean absolute error 0.04). Apparent and bias-corrected curves were closely aligned for both models, indicating minimal overfitting. Decision-curve analysis is shown in Figure 3. Both LIVERSTAT and FIB-4 provided greater net clinical benefit than the “treat-all” and “treat-none” strategies across a range of threshold probabilities. LIVERSTAT achieved a superior net benefit to FIB-4 between approximately 10–25% threshold probability, representing the clinically relevant range for referring patients for LSM.

LIVERSTAT and FIB-4 as a first-line test to identify patients for further evaluation with LSM for the diagnosis of cACLD

The use of LIVERSTAT and FIB-4 as a first-line test to identify patients for further evaluation using LSM for the diagnosis of cACLD is presented in Figure 3. When using LIVERSTAT as a first-line test to identify patients for further evaluation with LSM for the diagnosis of cACLD, the referral rate was 17% and the false negative rate was 19%. When using FIB-4 as a first-line test to identify patients for further evaluation with LSM for the diagnosis of cACLD, the referral rate was 24% and the false negative rate was 19%. The median (IQR) LSM among patients with false negative LIVERSTAT and FIB-4 was

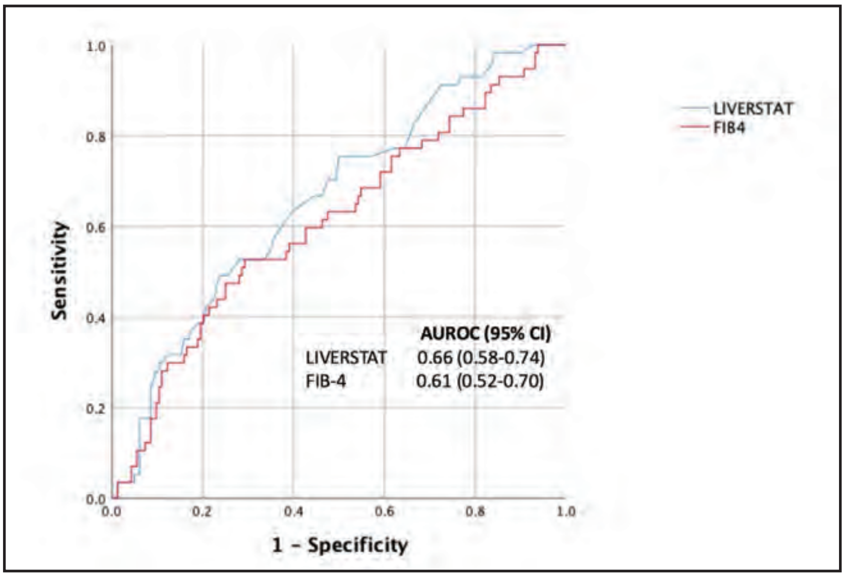

Fig. 1: Area under receiver operating characteristics curve of LIVERSTAT and Fibrosis-4 index for the diagnosis of compensated advanced chronic liver disease

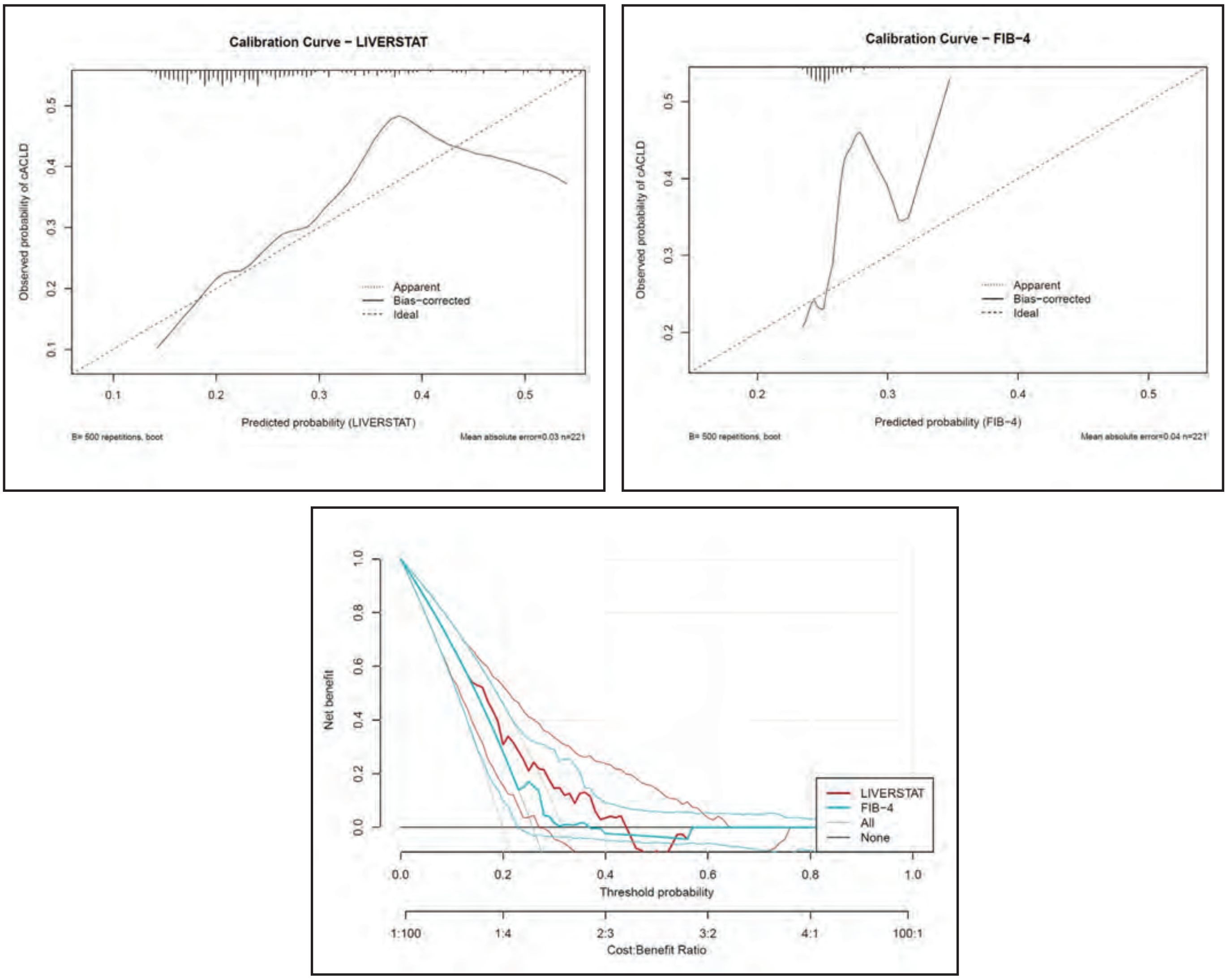

Fig. 2: Calibration plots for (a) LIVERSTAT and (b) FIB-4, and (c) decision-curve analysis for LIVERSTAT and FIB-4, for the diagnosis of cACLD

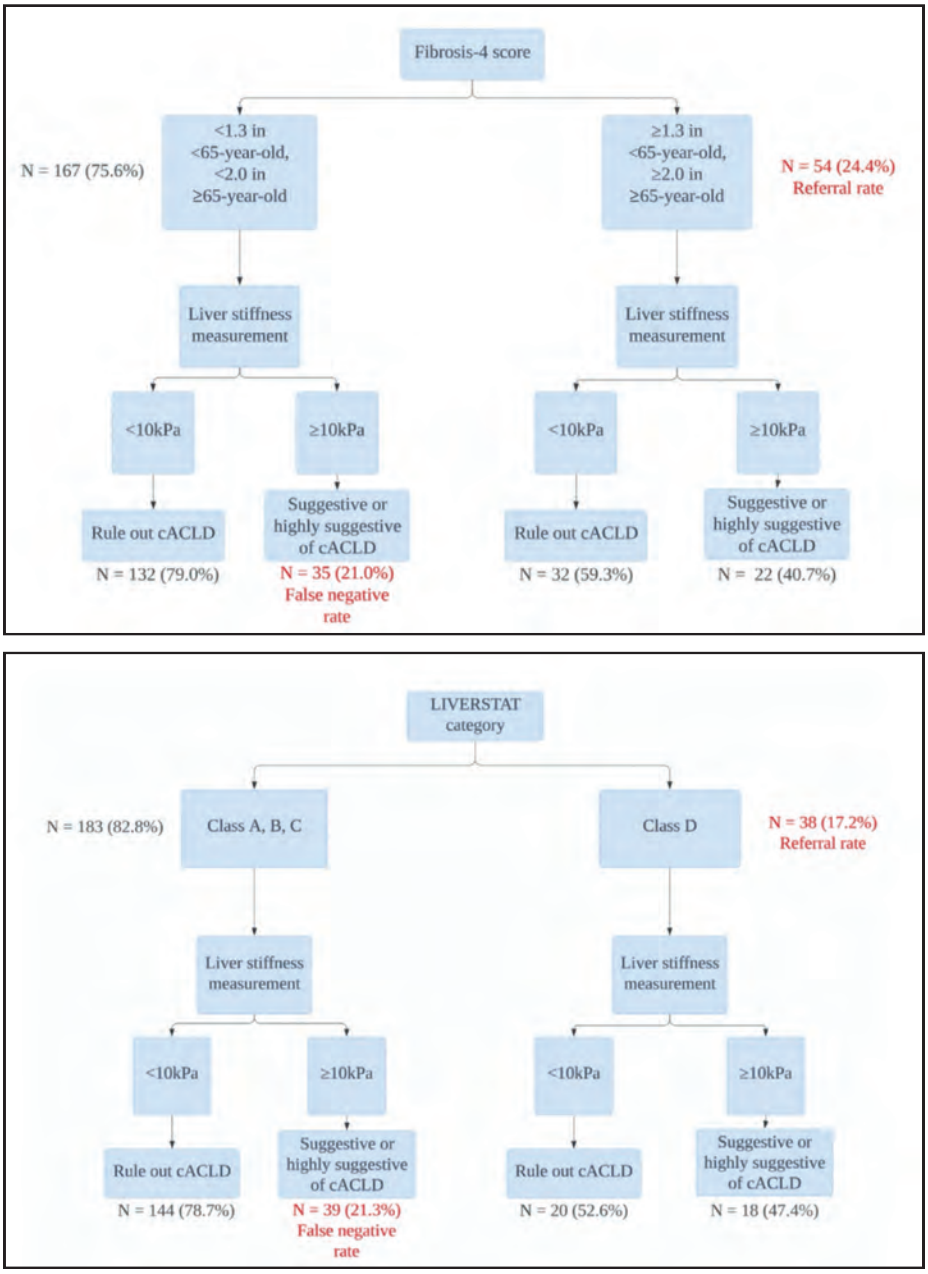

Fig. 3: Distribution of patients according to (a) LIVERSTAT and liver stiffness measurement, and (b) Fibrosis-4 index and liver stiffness measurement. Referral rates and false negative rates highlighted in bold

12.2 (10.9-17.2) kPa and 11.8 (10.8-16.0) kPa, respectively. Among patients with false negative LIVERSTAT, the proportion of patients with LSM 10-15 kPa and ≥15 kPa was 68% and 32%, respectively. Among patients with false negative FIB-4, the proportion of patients with LSM 10-15 kPa and ≥15 kPa was 71% and 29%, respectively.

LIVERSTAT for the diagnosis of significant hepatic steatosis

The sensitivity, specificity, positive predictive value, negative predictive value and misclassification rate of LIVERSTAT for the diagnosis of significant hepatic steatosis were 70%, 75%, 93%, 34% and 29%, respectively. The status of significant hepatic steatosis according to LIVERSTAT categories is shown in Table II.

DISCUSSION

In this study on patients with T2D, we found that LIVERSTAT exhibited a similar performance to FIB-4 as a stand-alone diagnostic test for cACLD and as a first-line test to identify patients for further evaluation with LSM for the diagnosis of cACLD. Although the accuracy of LIVERSTAT and FIB-4 as a stand-alone test for the diagnosis of cACLD was considered poor based on their AUROCs of <0.70, the tests demonstrated fairly high specificity of 81-88%. Both LIVERSTAT and FIB-4 demonstrated acceptable calibration, with minimal divergence between predicted and observed probabilities. This indicates that, despite their modest AUROC values, the predicted risks generated by each test are reasonably aligned with actual cACLD. Decision-curve analysis further supported the potential clinical utility of these tools. Both LIVERSTAT and FIB-4 provided greater net benefit than 'treat-all' or 'treat-none' strategies across a broad range of threshold probabilities. Notably, LIVERSTAT offered a higher net benefit than FIB-4 between approximately 10–25%, which aligns with the threshold range where clinicians typically consider referral for LSM. This suggests that LIVERSTAT may provide modest but meaningful improvement in triage efficiency in diabetes clinic settings.

The use of non-invasive tests to stratify the severity of chronic liver disease has been incorporated into international guidelines and clinical practice, notably the sequential use of FIB-4 followed by LSM for MASLD.[8-13] The fairly high specificity positions LIVERSTAT and FIB4 as potentially useful first line tests to identify T2D patients who are unlikely to have cACLD, who can then be managed in primary care or non-liver specialist clinics, with only a small proportion of patients requiring referral for further evaluation with LSM. This can help control the burden and cost in the implementation of assessment and referral pathways for MASLD in patients with T2D. Earlier identification of patients with more severe liver disease enables more intensive lifestyle interventions and pharmacological therapy that can alter the natural history of the disease and improve patient outcome. While performing LSM on all patients with T2D is an option, this is associated with access concerns in resource-limited settings and where the test is not reimbursed. In our study, the use of LIVERSTAT or FIB-4 as a first-line test translated to a referral rate for further evaluation with LSM of only 17-19%. On the other hand, the use of LIVERSTAT or FIB-4 as a first-line test was associated with a false negative rate of 19%. However, most of the patients with false negative results had LSM 10-15 kPa and would be considered as only having the possibility of cACLD as opposed to assumed cACLD with LSM ≥15 kPa.[6 18] Furthermore, patients with LSM 10-15 kPa have lower rates of liver-related events compared with patients with LSM ≥15 kPa.[18]

We observed some differences in the results of this study when compared with other recent studies on LIVERSTAT and FIB-4.[14,19] In both studies, LIVERSTAT and FIB-4 were found to have better diagnostic accuracy for the diagnosis of advanced liver fibrosis, with an AUROC of 0.79 for both tests in one study, and an AUROC of 0.76 for both tests in the other study.[14,19] Although LIVERSTAT and FIB-4 were found to have similar diagnostic accuracy, the use of LIVERSTAT was associated with a higher referral rate and a lower false negative rate compared with FIB-4.[14] These observed differences may be due to differences in patient characteristics and the different reference standard that was used. The current study consists of only patients with T2D, whereas previous studies included patients without T2D. The performance of non-invasive tests may be different in patients with and without T2D.[20] Furthermore, the previous studies used histology, i.e. advanced liver fibrosis based on liver biopsy, as the reference standard, whereas the current study used LSM as the reference standard in line with the concept of cACLD. Besides the evaluation of fibrosis, LIVERSTAT was developed for the diagnosis of hepatic steatosis. To the best of our knowledge, this is the first study to report on the performance of LIVERSTAT for the diagnosis of significant hepatic steatosis in patients with T2D. We found LIVERSTAT to have poor negative predictive value for significant hepatic steatosis. This is likely due to the high prevalence of significant hepatic steatosis in patients with T2D and the limitation of anthropometric and laboratory data to distinguish between patients with and without significant hepatic steatosis in this population.

Despite our best efforts, this study had several limitations. Firstly, a relatively large number of patients from the original research project had to be excluded from this study due to missing data to calculate LIVERSTAT and/or FIB-4. Serum AST and platelet count were not yet routinely performed for patients with T2D in the diabetes clinic of our institution at that time. The high number of excluded patients introduces potential selection bias and may limit generalizability to the broader T2D population. Nevertheless, the sample size of 221 patients was considered reasonable as all included patients were well-characterised and the data were obtained prospectively. Secondly, we did not have a liver biopsy for the majority of patients and could not analyse the data using histology as the reference standard. Liver biopsy is an invasive procedure associated with a small risk of serious complications, including mortality.[21] Furthermore, the use of liver biopsy as a reference test is inherently limited by sampling variability and observer variability.[22–24] Therefore, the field of MASLD is moving towards the use of non-invasive tests.

CONCLUSION

In conclusion, LIVERSTAT demonstrated comparable diagnostic performance to FIB-4, both as a stand-alone tool and as a first-line test to select patients with T2D for further evaluation with LSM for the diagnosis of cACLD. Its relatively high specificity can help reduce referral for LSM. Further longitudinal studies are needed to evaluate the role of LIVERSTAT in prognostication and stratification of patients according to long-term liver-related outcomes. In addition, studies comparing LIVERSTAT with other non-invasive tests can help develop a better understanding of its use in different clinical settings. Overall, LIVERSTAT has the potential to be an alternative to FIB-4 in the clinical care pathway for patients with T2D and MASLD. However, due to its proprietary algorithm, the additional cost associated with using LIVERSTAT should be considered, especially with the free availability of alternative tests such as FIB-4.

CONFLICT OF INTEREST

WKC has served as a consultant for Abbott, Abbvie, Boehringer Ingelheim, IPSEN, Kowa, Novo Nordisk, Roche and Zuellig Pharma, a speaker for Abbott, Echosens, Hisky Medical, Novo Nordisk, Roche and Viatris, and received research grant from Abbott and Roche. The other authors have no conflict of interest to declare.

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