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Performance of Albumin-Bilirubin (ALBI) score in comparison to other non-invasive markers in the staging of liver fibrosis in chronic HCV patients

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Abstract

Background The prognostic ability of albumin-bilirubin score (ALBI) to assess the hepatic dysfunction in patients with hepatocellular carcinoma (HCC) was previously studied. Its role in the staging of liver fibrosis post chronic hepatitis C Virus (HCV) infection needs to be investigated.

Aim to assess the diagnostic value of the ALBI score compared to other non-invasive fibrosis scores in chronic HCV patients.

Methods This cross-sectional study included consecutive chronic HCV patients from January 2015 till December 2018. Liver stiffness measurement (LSM) by transient elastography (TE) is currently one of the most validated non-invasive methods for liver fibrosis staging and is used in daily practice as a reference for fibrosis assessment. ALBI grade as well as Fibrosis-4 (FIB-4), Aspartate aminotransferase to platelet ratio index (APRI), LOK index and Göteborg University Cirrhosis (GUCl) scores were calculated for all of the patients.

Results A total of 781 chronic HCV patients were included. Around 54% of them had compensated cirrhosis. GUCl score was the most sensitive one to difference between early fibrosis stages, F0 vs. F1. LOK index and ALBI score did not differ significantly between F1 and F2 stages unlike the other study markers. ROC curves revealed good diagnostic capability of FIB-4 (AUROC: 0.85, 0.84), APRI (AUROC: 0.83, 0.83) and GUCl score (AUROC: 0.83, 0.83) for detecting advanced fibrosis and cirrhosis, respectively. ALBI score had a moderate diagnostic role for diagnosing advanced fibrosis and cirrhosis, AUROC of 0.73 and 0.74 respectively. At a cutoff value of -2.95, the sensitivity of ALBI score approached 79%, the specificity was 53% for advanced fibrosis.

Conclusion ALBI score has a moderate diagnostic power score in the diagnosis of HCV-associated advanced liver fibrosis and cirrhosis; however, FIB-4, APRI and GUCl scores outperformed the ALBI score.

Keywords Chronic hepatitis C, Liver fibrosis, Albumin-Bilirubin (ALBI) score, Non-invasive markers

Introduction

Liver fibrosis is an important public health issue which represents the end result of sustained liver injury usually from multiple, simultaneous factors. Assessment of the degree of liver fibrosis is of paramount importance in the management of patients with chronic liver disease (CLD) [1] as it is important for decision making regarding the

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initiation of therapy (e.g., antivirals for hepatitis B [HBV] or hepatitis C [HCV]) and surveillance strategies for hepatocellular carcinoma [HCC] and esophageal varices in patients with cirrhosis as well as predicting the prognosis [2].

Although liver biopsy is the traditional method of reference for assessment of the degree of liver fibrosis in patients with CLD, it should be reserved for certain cases where more accurate fibrosis staging would impact treatment decisions due to its invasiveness and potential to cause significant complications [3, 4]. Accordingly, there was a necessity to develop non-invasive methods to assess liver fibrosis resulting in dramatically enhanced clinical decision making in patients with CLD [1]. These methods incorporated imaging-based techniques (transient elastography, shear wave elastography, magnetic resonance elastography) as well as serum-based indices which have been increasingly used in routine practice. With continuous progress in the reliability, reproducibility and feasibility of these non-invasive methods, their potential role in disease management has been expanded [1].

Transient elastography (TE), an ultrasound-based elastography, is increasingly used for the measurement of liver stiffness (LS) as an alternative to liver biopsy. TE is well validated in viral hepatitis with performance equivalent in hepatitis B, C and HIV/HCV co-infection [5]. Its main limitation is the non-feasibility of obtaining results in case of ascites or morbid obesity as well as the device is expensive and not widely available [6]. Consequently, several serum biomarkers were developed as non-invasive methods using simple and inexpensive routine laboratory tests to determine liver fibrosis stages. The fibrosis-4 (FIB-4) index and aspartate aminotransferase to platelet ratio index (APRI) are commonly used to determine liver fibrosis stages using age and serum biochemistry such as aspartate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count [7, 8]. Other biological scores including Lok index and Göteborg University Cirrhosis (GUCI) score are also used; these scores calculated from standard biological tests that are used in daily practice such as serum AST, ALT, international normalized ratio of prothrombin (INR) and platelet count [9]. Recently, the albumin–bilirubin (ALBI) score was basically developed to predict prognosis in patients suffering from liver cirrhosis with or without hepatocellular carcinoma (HCC) [10]. According to this score, which is calculated based solely on serum total bilirubin (T-Bil) and albumin (Alb) alone, patient prognosis is classified into one of three grades, called the ALBI grade. However, the diagnostic accuracy of the ALBI score when used for liver fibrosis staging in patients with chronic hepatitis has not been investigated well [11].

This study aims to evaluate the performance of the ALBI score in comparison to other non-invasive markers in the staging of liver fibrosis in chronic HCV patients using transient elastography (TE) as a reference method.

Materials and methods

Participants

This cross-sectional study included consecutive 781 chronic HCV patients attending Kasr Al-Aini Viral Hepatitis Center, Cairo University from January 2015 till December 2018. Patients aged 18–75 years with seropositivity for HCV antibodies and detectable HCV RNA for more than 6 months were eligible for this study. Patients who had concomitant HBV or human immunodeficiency virus infection, underlying liver disease e.g. autoimmune hepatitis, decompensated liver cirrhosis, and hepatocellular carcinoma, or extra-hepatic malignancy were excluded. Additionally, patients in whom TE examinations could not be performed were excluded.

The demographic, clinical data and routine laboratory work-up were extracted from the participants' medical records including: age, gender, body mass index [BMI], presence of cirrhosis, and laboratory tests (complete blood counts, liver biochemical profile (serum transaminases (AST, ALT), total serum bilirubin (TSB), serum albumin, the international normalized ratio [INR]). The upper limit of normal (ULN) for aminotransferase level (ALT and AST) was defined as 40 IU/L. In addition, ultrasound scan of abdomen was done to assess the general hepatic condition and to exclude ascites or focal hepatic lesions. For each patient, liver stiffness measurements (LSM) were assessed by TE using the M probe for patients with BMI < 30 kg/m² and the XL probe for patients with BMI ≥ 30 kg/m². Non-invasive fibrosis scores were also calculated.

Transient elastography

LS was assessed by TE using FibroScan[®] 502 (EchoSens, Paris, France). The same technical background and examination procedures were done according to the standards of the manufacturer's recommendations [12]. Ten valid measurements were performed, and the median of LS was expressed in kilopascals (kPa). Results were considered reliable if the success rate was ≥ 60% and the interquartile range (IQR) was < 30% of the median value (M) of LSM (IQR/M ≤ 0.30%). In this study, TE was considered as the reference method for liver fibrosis evaluation to which the performance of the ALBI score was compared. Staging of liver fibrosis was established by TE according to predefined thresholds as follows: < 7.1 kPa for non-significant fibrosis (F < 2), ≥ 7.1 kPa for significant fibrosis (F ≥ 2), 9.5 kPa for advanced

fibrosis ($F \geq 3$), and ≥ 12.5 kPa for liver cirrhosis (F4) [5, 13]. The operator was blinded to the patients' clinical and laboratory data.

Calculated scores for assessing fibrosis

These scores were selected based on the criteria of being simple and inexpensive routine laboratory tests.

- a) ALBI score was calculated using the formula [10]:

$$\text{Log}_{10} \text{ total bilirubin } (\mu\text{mol/L}) \times 0.66 + \text{albumin } (\text{g/L}) \times (0.085).$$

- b) APRI score was calculated using Wai's formula [8]:

$$(\text{AST}/\text{upper limit of normal}) / \text{Platelet count } (10^9/\text{L}) \times 100.$$

- c) FIB-4 score was calculated using Sterling's formula [7]:

$$\text{Age (years)} \times \text{AST (IU/L)} / \text{platelet count } (10^9/\text{L}) \times \sqrt{\text{ALT (IU/L)}}.$$

- d) GUCI, calculated using the formula [14]:

$$\text{AST (Upper Limits of Normal)} \times \text{INR} \times 100 / \text{platelet count } (\times 10^9/\text{L}).$$

- e) Lok score, calculated using the formula [15]:

$$\text{Log odds} = -5.56 - 0.0089 \times \text{number of platelets } (10^3/\text{mm}^3) + 1.26 \times (\text{AST}/\text{ALT}) + 5.27 \times \text{INR}.$$

$$\text{Lok} = [\exp(\text{log odds})] / [1 + \exp(\text{log odds})].$$

The study was approved by the Institutional Review Board (IRB) of the Faculty of Medicine, Cairo University. Written informed consent was obtained. The study was designed to respect all the ethical guidelines of the 1975 Declaration of Helsinki and its later amendments with Good Clinical Practice (GCP) guidelines.

Statistical analysis

For descriptive statistics, mean (SD) or median (IQR) were used for numerical data and frequency (percentage) was used for categorical data. The distribution of data was tested using the Shapiro-Wilks test. The t test was used for the comparison of normally distributed numerical variables between the two independent groups; while the Mann-Whitney test was used in case of non-normal distribution. ROC curves were constructed to assess the diagnostic value of the non-invasive fibrosis markers in detecting advanced fibrosis and liver cirrhosis. P values < 0.05 are considered significant. STATA 15.1 (Copyright 1985–2017 StataCorp LLC) statistical program was used for the analysis.

Results

Patients' characteristics

The main characteristics of the studied patients are outlined in Table 1. The median age of the study patients was 55 years (range 23–72) with male predominance (62.48%). Stages of hepatic fibrosis based on LSM using TE as the reference method were as follows; 108 (13.8%) patients had F0, 56 (7.17%) had F1, 101 (12.9%) had F2, 95 (12.16%) had F3 and 421 (53.9%) had F4. The median values of the ALBI score, FIB-4 score, APRI score, LOK index, and GUCI score were -2.77, 2.27, 0.78, 0.51, and 0.88, respectively.

Performance of the ALBI score and the conventional non-invasive fibrosis indices for hepatic fibrosis staging

The median values of the ALBI score, FIB-4, APRI score, LOK index, and GUCI score for different fibrosis stages are presented in Fig. 1. There was a significant difference in the ALBI score between F4 vs F3 ($P = < 0.0001$) but no significant difference in its value was observed when comparing between no to moderate degree of fibrosis

Table 1 Baseline patients' criteria ($n = 781$)

Variables	Median (IQR)/ Number (%)
Age (years)	55 (48–60)
Gender, Male n (%)	488 (62.48%)
BMI (Kg/m^2)	29.34 (26.57–32.7)
Laboratory parameters	
WBCs	5.7 (4.6–7.1)
Hemoglobin	14.2 (12.9–15.4)
Platelets	160 (125–218)
ALT	48 (33–75)
AST	46 (32.8–69)
Total bilirubin	0.7 (0.5–0.9)
Albumin	4.1 (3.7–4.4)
INR	1.1 (1.01–1.2)
HCV RNA	654×10^3 (162133–186 $\times 10^4$)
Fibrosis stages	
F0	108 (13.8%)
F1	56 (7.17%)
F2	101 (12.9%)
F3	95 (12.16%)
F4	421 (53.9%)
Liver fibrosis parameters	
FIB-4	2.27 (1.40–3.49)
APRI	0.78 (0.47–1.37)
ALBI score	-2.77 (-3.05– -2.43)
LOK index	0.51 (0.32–0.70)
GUCI	0.88 (0.50–1.55)
Liver stiffness	13.8 (7.7–23.4)

Numerical data presented as median (IQR)

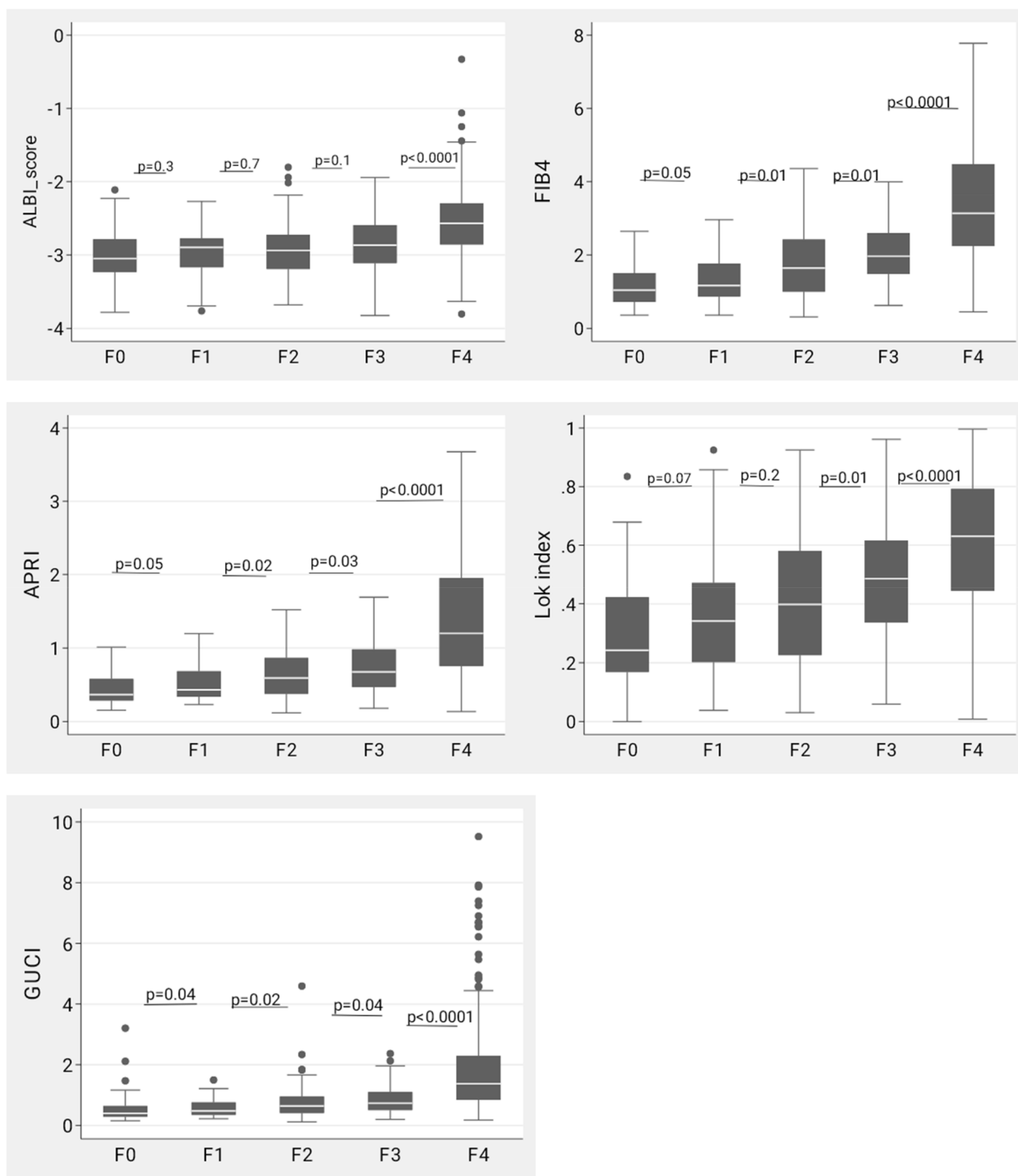


Fig. 1 Boxplot showing the values of non-invasive fibrosis markers (ALBI, FIB-4, APRI, LOK index, GUCI score) in different stages of fibrosis

(F0-F2) with advanced fibrosis and cirrhosis (F3-F4) and between F3 and F2, F2 and F1, and F1 vs F0 ($P=0.1, 0.7,$ and $0.3,$ respectively). The other non-invasive fibrosis indices were more sensitive to difference in earlier fibrosis stages e.g. FIB-4 score, APRI score, LOK index, and

GUCI score significantly differed between F3 and F2 and between F4 and F3 as shown in Fig. 1.

Receiver operating characteristics (ROC) curves were performed to determine the best cut-off values for the ALBI score in discriminating advanced fibrosis (F3)

and cirrhosis (F4). As shown in Table 2, the AUROC of ALBI score was 0.73 and 0.74 in identifying F3 and F4 respectively. At Cut-off value of -2.95, the sensitivity was 77.78%, specificity was 52.83% and accuracy was 70.04% for predicting advanced fibrosis (F3). At a cut-off of -2.91, the sensitivity was 80.05%, the specificity was 53.3% and accuracy 67.73% for predicting cirrhosis (F4).

The AUROC for FIB-4, APRI, and GUCI scores showed good accuracy in the detection of advanced fibrosis (F3) and liver cirrhosis. The AUROC values were 0.85(0.82–0.88) and 0.84 (0.82–0.87) for FIB-4, 0.83 (0.79–0.85) and 0.83 (0.80–0.86) for APRI score, and 0.83(0.80–0.85) and 0.83 (0.80–0.86) for GUCI score for advanced fibrosis and cirrhosis respectively. LOK index showed fair accuracy in advanced fibrosis and cirrhosis detection, AUROC value of 0.77 and 0.76 as shown in (Table 2 and Figs. 2 and 3).

Discussion

Several non-invasive tests have been developed and have revolutionized the way we diagnose liver fibrosis for their safety, easy-to-perform, and good reliability and feasibility. This leads the researchers to expand their role in disease management and has driven much attention in evaluation of novel innovative markers [1].

This study aimed at evaluating the performance of the ALBI score as a non-invasive marker for assessment of advanced hepatic fibrosis and liver cirrhosis and comparing its value to other non-invasive fibrosis markers; FIB-4 and APRI scores, using TE as a reference method. Additionally, the GUCI score and LOK index were investigated.

The ALBI score has been initially reported by Johnson et al. to estimate liver function status in patients with HCC and to stratify them into categories at different risk stages [10]. Since ALBI-based score has been shown to be an independent prognostic factor for survival and have a similar or a better prognostic performance to Child–Pugh (CP) and MELD scores in patients with HCC; [16, 17] therefore, researchers are encouraged to assess the accuracy of the ALBI score in predicting outcomes in liver diseases other than HCC such as primary biliary cholangitis [18], hepatitis B [19], acute upper gastrointestinal bleeding [20] and acute-on-chronic liver failure [21]. However, to date only a few studies evaluated the role of ALBI score as a novel marker of non-invasive assessment of hepatic fibrosis in chronic hepatitis C [11].

In the present study, we found that the ALBI score was significantly higher in patients with liver cirrhosis compared to those with F3 stage ($P = < 0.0001$); nonetheless, it did not show significant difference between each two of the earlier fibrosis stages. We could also demonstrate that the ALBI score exhibited a fair diagnostic ability in detecting advanced fibrosis (F3) and liver cirrhosis (F4)

Table 2 Performance of non-invasive fibrosis markers in the detection of advanced hepatic fibrosis

		Advanced fibrosis (F3)	Cirrhosis (F4)
ALBI score	AUC (95%CI)	0.73 (0.69–0.77)	0.74 (0.71–0.78)
	Best cut-off	-2.95	-2.91
	Specificity	52.83	53.33
	Sensitivity	78.88	80.05
	LR+	1.67	1.71
	LR-	0.40	0.37
	Accuracy	70.04	67.73
FIB-4 score	AUC (95%CI)	0.85 (0.82–0.88)	0.84 (0.82–0.87)
	Best cut-off	1.8	3.25
	Specificity	73.21	93.3
	Sensitivity	82.17	46.8
	LR+	3.07	7.02
	LR-	0.24	0.57
	Accuracy	79.13	68.3
APRI score	AUC (95%CI)	0.83 (0.79–0.85)	0.83 (0.80–0.86)
	Best cut-off	0.6	0.72
	Specificity	63.02	71.7
	Sensitivity	81.01	77.2
	LR+	2.19	2.72
	LR-	0.30	0.32
	Accuracy	74.9	74.65
LOK index	AUC (95%CI)	0.77 (0.74–0.81)	0.76 (0.73–0.79)
	Best cut-off	0.4	0.41
	Specificity	60.38	57.22
	Sensitivity	80.04	80.29
	LR+	2.02	1.88
	LR-	0.33	0.34
	Accuracy	73.37	69.65
GUCI score	AUC (95%CI)	0.83 (0.80–0.85)	0.83 (0.80–0.86)
	Best cut-off	0.52	0.61
	Specificity	54.34	55
	Sensitivity	88.18	87.17
	LR+	1.93	1.94
	LR-	0.22	0.23
	Accuracy	76.70	72.34

Abbreviations: ALBI Albumin-Bilirubin, FIB-4 Fibrosis-4, APRI Aspartate aminotransferase to Platelet Ratio Index, GUCI Göteborg University Cirrhosis Index

with an AUROC values of 0.73 (0.69–0.77) and 0.74 (0.71–0.78) respectively.

Compared to FIB-4 and APRI scores, ALBI score has lower AUROC in distinguishing advanced fibrosis as well as cirrhosis. The AUROC for detecting cirrhosis were 0.84 (0.82–0.87) for FIB-4 and 0.83 (0.80–0.86) for the APRI score.

Our results agreed with Fujita et al., who demonstrated fair diagnostic ability for the ALBI score in distinguishing

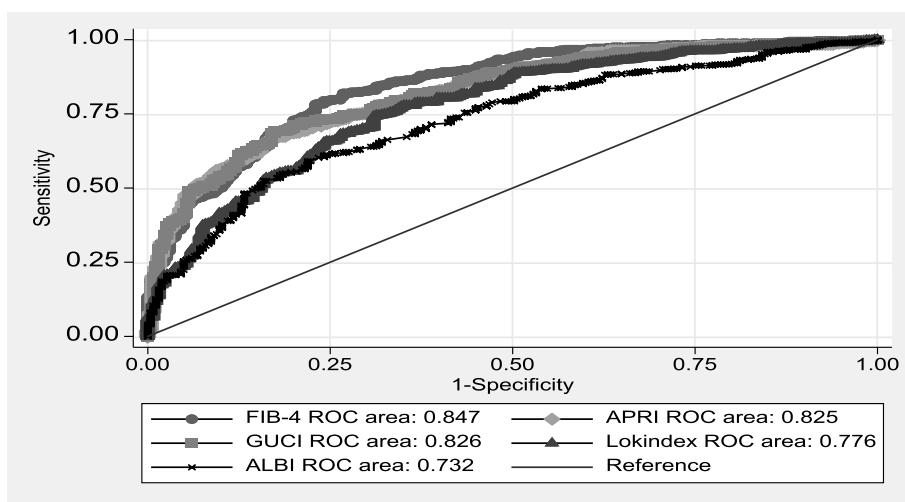


Fig. 2 ROC curves for the discriminatory power of fibrosis markers in detecting advanced fibrosis (F3)

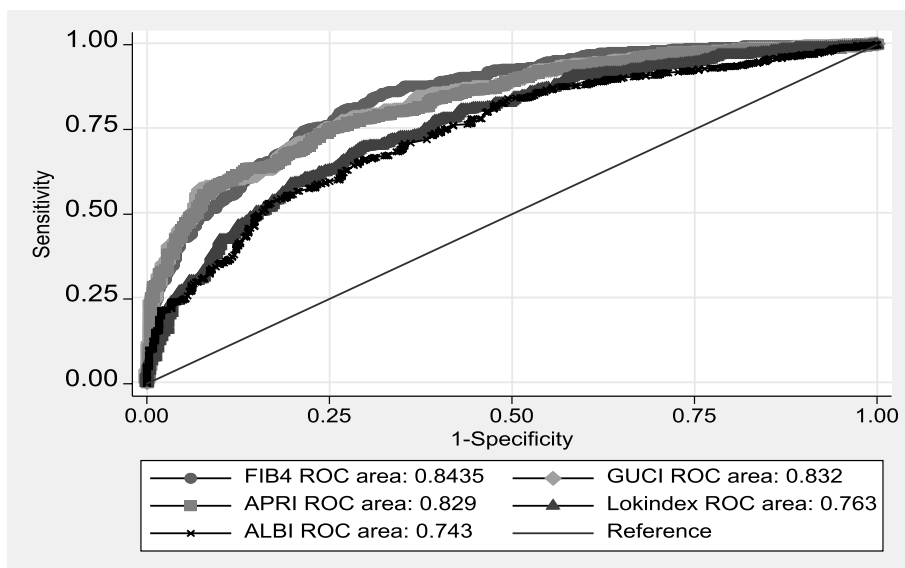


Fig. 3 ROC curves for the diagnostic ability of non-invasive fibrosis markers in diagnosing cirrhosis (F4)

advanced fibrosis with an AUROC between 0.7 and 0.8, which was smaller than those of the FIB-4 and APRI scores. On the contrary, they showed a good performance in distinguishing cirrhosis from non-cirrhosis (AUROC between 0.8 and 0.9) which was comparable to FIB-4 and APRI scores [11], unlike what was found in our study. Moreover, another study showed that the ALBI score has a moderate diagnostic ability in HBV patients, distinguishing cirrhotic from non-cirrhotic status with an AUROC of between 0.8 and 0.9 [22].

ALBI score was also assessed in another study which showed its good ability in detection of advanced fibrosis and cirrhosis in Egyptian patients with HCV. They

identified a cut off value of -2.781 as a predictor of advanced liver fibrosis and cirrhosis with an AUROC of 0.832 showing a sensitivity of 74.8%, specificity of 80.2%, PPV 86.8%, NPV 64.6% and positive likelihood ratio = 3.77 [23].

The best cut-off values for ALBI score in our study were -2.95 (sensitivity 78.9% and specificity 52.8%) and -2.91 (sensitivity 80.1% and specificity 53.3%) for diagnosing advanced fibrosis and cirrhosis respectively.

On the other hand, there was no significant difference in ALBI score in the current study between moderate and mild fibrosis which was contradictory to what was shown by Fujita and his colleagues who stated that there was a

significant difference in ALBI levels between patients with a fibrosis stage of F3 compared to those with a stage of F2 [11].

The ALBI score differs from other fibrosis indices that it does not include platelets, hepatic transaminases or age. The diagnostic accuracy of the ALBI score for liver fibrosis staging is preserved in thrombocytopenic patients caused by diseases not related to liver fibrosis, such as idiopathic thrombocytopenia and drug-induced thrombocytopenia. A potential weakness of the ALBI score is that it depends on serum albumin in its equation which its level could be influenced by other disease such as glomerulonephritis.

The limitations of the study include its retrospective nature, lack of assessment of the prognostic role of the ALBI score in this cohort added to its limitation to patients with chronic HCV infection disallowing its application in liver diseases of other etiologies. In addition, liver biopsy which remains the gold standard for assessment of liver fibrosis and cirrhosis was not performed which would have been more accurate as a reference method.

Conclusion

Evaluation of different serum fibrosis biomarkers is necessary for non-invasive assessment of liver status. ALBI score despite being a tool estimating the degree of liver fibrosis, it did not appear to add more value to the other indices currently used in practice.

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NA

Code availability

N/A.

Authors' contributions

MB made substantial contributions to the conception and design of the work. He approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. SA made substantial contributions to the conception of the work. She approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. AE made substantial contributions to the conception and design of the work. She approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. RF made substantial contributions to the conception of the work. She approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. GE made substantial contributions to the conception of the

work. He approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. ZA made substantial contributions to the conception of the work. She approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Availability of data and materials

All data generated or analysed during this study are included in this published article.

Declarations

Ethics approval consent to participate

The study was accepted by the investigational review board (IRB) of Cairo University.

All patients signed informed consent.

Consent for publication

All authors accept publication.

Competing interests

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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