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FIB-4 Score Is Correlated With Liver Fibrosis but Not With Liver Steatosis: A Cross-Sectional Study in Persons Living With T2DM

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Abstract

Aim: The present study was conducted to evaluate the corelation between Fibrosis-4 score (FIB-4) in cases of Liver fibrosis as well as Liver steatosis in comparison to other liver fibrosis assessment scores.

Methodology: Cross-sectional study was conducted amongst 352 participants who had type 2 diabetes mellitus (T2DM). FIB-4 score and Non-alcoholic fatty liver disease (NAFLD) fibrosis score (NFS) were calculated using blood parameters. Liver Stiffness Measurement (LSM) scores along with Controlled Attenuation Parameter (CAP) scores were calculated using Vibration Controlled Transient Elastography (VCTE). Spearman's correlation estimates were used to evaluate these fibrosis scores of FIB-4, NFS and LSM in Metabolic dysfunction associated steatotic liver disease (MASLD) patients.

Results: Out of a total cohort of 352 persons, 75% had steatosis and 27.1% had fibrosis based on the findings of VCTE. According to prediction based on FIB- 4, 10.8% had fibrosis, and based on the NFS 23.4% had fibrosis. Our data revealed a positive correlation between the FIB-4 score and LSM by VCTE ($r = 0.22$, $p < 0.001$).

Conclusion: Beyond its risk assessment, FIB-4 serves as a prognostic biomarker with clinical significance. This straightforward scoring system can act as an early warning signal, helping to identify patients who are at risk for advanced liver fibrosis and may need referral to specialized medical care.

Keywords: Chronic liver disease; liver fibrosis; MASLD; screening; fibrosis 4 score.

Introduction

Chronic liver disease is a leading global cause of death and places a significant burden on healthcare systems. The underlying causes of liver disease vary by region and age, with viral hepatitis, metabolic dysfunction associated steatotic liver disease (MASLD), and excessive alcohol consumption being the most prevalent contributors. It is estimated that over 1.3 billion people worldwide suffer from chronic liver disease, resulting in more than 2 million liver-related deaths annually, which represents 3.5% of global mortality [1,2]. Liver fibrosis plays a crucial role in the progression to liver cirrhosis

and hepatocellular carcinoma (HCC), and it is essential for determining prognosis and treatment strategies [3,4]. Early detection of liver disease, particularly in primary care settings, is vital for improving outcomes. Traditionally, liver disease diagnosis relies on liver biopsy, which, although considered the gold standard for histopathological evaluation, is invasive, expensive, and associated with risks such as pain, bleeding, and even mortality [5]. Additionally, liver biopsy has limitations, including sampling error and variability between observers [6,7].

Consequently, researchers have developed various non-invasive alternatives over recent decades (Figure 1). Non-invasive methods, such as positron emission tomography (PET), magnetic resonance (MR) imaging, and notably, vibration controlled transient elastography (VCTE), have been proposed. VCTE, an advanced ultrasound-based technique, can assess both liver steatosis and liver fibrosis simultaneously, and has been found to be cost-effective, [8,9]; however, it is not universally available, and its accuracy can be affected by factors such as obesity, ascites and timing of testing [10.11.12]. Ultrasound effectively detects steatosis when more than 33% of hepatocytes are affected but may be less reliable for milder cases. Fibrosis-4 Index (FIB-4) is a non-invasive tool for assessing advanced liver fibrosis, and recent studies suggest it performs comparably or even better than some other fibrosis biomarkers, including the enhanced liver fibrosis (ELF™) test [13]. FIB-4 is widely endorsed by international guidelines for initial assessments in MASLD and type 2 diabetes (T2DM) and is recommended for periodic reassessment based on disease severity and cardiometabolic risk factors [14]. Although some research has linked FIB-4 to mortality and liver-related outcomes in MASLD, these studies often involve small sample sizes and selective populations [15,16]. There is a requirement for additional studies in usual primary care settings to sustain the practical application of clinical guidelines.

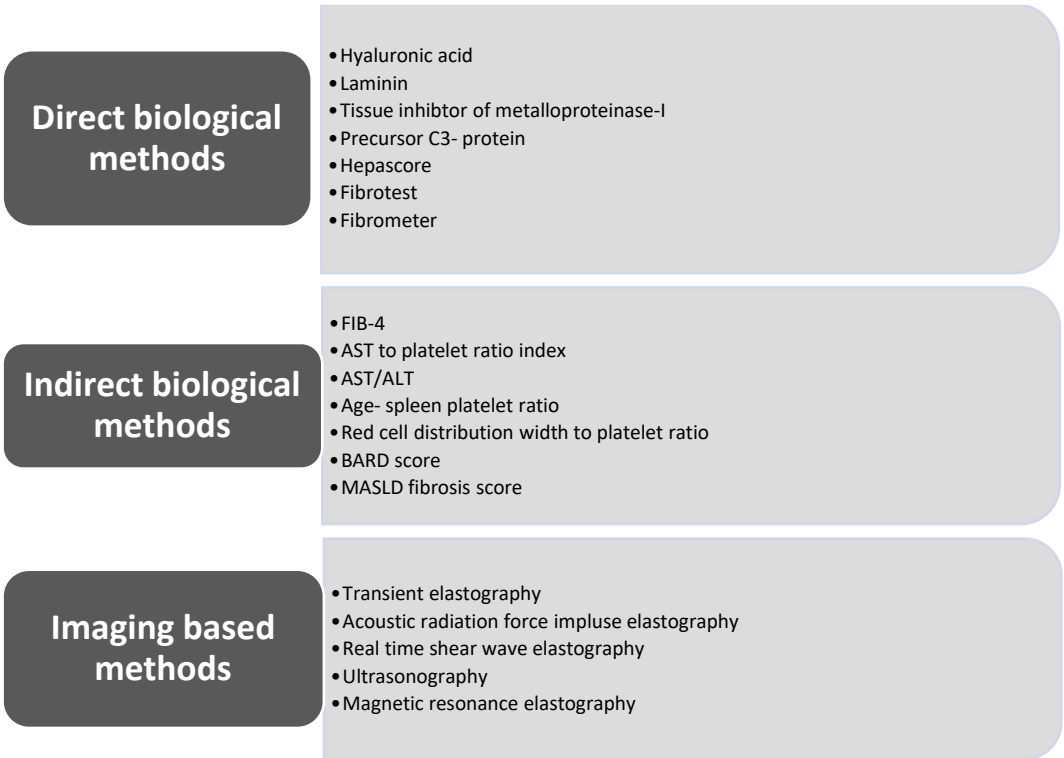

Figure 1- Common non-invasive methods for detecting liver fibrosis. (FIB-4, fibrosis index; AST, aspartate aminotransferase; ALT, alanine aminotransferase; GGT, γ-glutamyl transferase; MASLD, Metabolic dysfunction associated steatotic liver disease, (BARD, trio index of BMI >28kg/m^2-AST/ALT >0.8- Diabetes), C3, Complement component 3.)

Methodology

Objective of the study:

Purpose of the present research was to assess the corelation between FIB-4 score, NFS , Liver steatosis, and Liver fibrosis. Also predisposing factors like- liver enzymes, Body Mass Index (BMI), waist circumference, glycemic aberrations and dyslipidemia were also studied in correlation to progression of MASLD.

Study design:

A cross-sectional study was carried out with 352 participants at seven secondary-level specialty clinics in Lucknow, India, from June 2022 to December 2022. Patients with T2DM attending these clinics for routine check-ups were invited to participate, and those who consented were included in the study.

Clinical parameters such as Glycosylated Haemoglobin (HbA1c), fasting plasma glucose (FPG), postprandial plasma glucose (PPG), complete blood count (CBC), liver function tests (LFT), kidney function tests (KFT), and lipid profiles were evaluated. Additionally, all eligible participants underwent Vibration Controlled Transient Elastography (VCTE) of the liver.

Inclusion Criteria

Individuals aged 18 years or older with a confirmed diagnosis of type 2 diabetes mellitus (T2DM) who consented to undergo VCTE using a FibroScan^{TM} device. Patients who had reports of HbA1c and either FPG, PPG, or random plasma glucose (RPG), LFT, CBC and lipid profile measurements along with the VCTE.

Exclusion Criteria

Participants with type 1 diabetes mellitus (T1DM). Patients lacking the required blood test results. Patients consuming alcohol in amounts exceeding the limits defined by the American Association for the Study of Liver Diseases (AASLD); Asian guidelines. Patients with positive test results for either Hepatitis B surface Antigen (HBsAg) or Hepatitis C antibody (anti-HCV).

Clinical Measurement:

Liver steatosis and fibrosis measurements were performed using the VCTE method with a FibroScan^{TM} device (Echosense,Paris,France). A single certified technician, who had conducted numerous assessments independently, carried out all the examinations. Each patient was fasted for 3 hours prior to the procedure. The probe was positioned between the intercostal spaces over the right hepatic lobe while patients were in a dorsal decubitus position with their right arm fully extended. Initially, both M and XL probes were employed, with the M probe used for patients with a normal BMI and the XL probe for those with obesity.

For each patient, ten valid readings were recorded, and the median value was used to represent the liver stiffness in kilopascals (kPa) and liver steatosis in decibels per meter (dB/m). The interquartile range (IQR) of LSM, which encompasses 50% of the valid measurements between the 25th and 75th percentiles, was also noted. The success rate was determined by the ratio of valid acquisitions to the total number of acquisitions. LSM was consistent if at least ten proper measurements were obtained, and the IQR-to-median ratio was ≤0.3. Both liver steatosis and liver fibrosis are measured simultaneously with Controlled Attenuation Parameter (CAP) score as a surrogate marker for steatosis and Liver Stiffness Measurement (LSM) as a surrogate marker for fibrosis. The participants were categorized into 3 steatosis groups based on CAP score S1 >238-259, S2 260-291, S3 >292 and 5 fibrosis groups based on LSM score F0-F1 <8 kPa, F2: 8-10kpa, F3: 10-14kPa and F4 >14kPa.

T2DM was diagnosed using American Diabetes Association (ADA) criteria, which included FPG >125 mg/dL, (PPG) >199 mg/dL, or HbA1c >6.4%. BMI was calculated as body weight in kilograms divided by the square of height in meters, with height measured to the nearest 0.5 cm and weight to the nearest 0.1 kg. Waist circumference was evaluated according to the International Diabetes Federation (IDF) criteria for the Asian population, with level of 80 cm for females and 90 cm for males.

Statistical Analysis:

Descriptive statistics for categorical variables are presented as means ± standard deviation (SD) or medians with interquartile ranges (IQR), while

percentages are used for other variables. Spearman's correlation coefficients were employed to analyse relationships between various factors and NFS or fibrosis parameters. Pairwise comparisons of means were performed using Student's t-test, and proportions were analysed with the Chi-square test, with statistical significance set at a 5% level.

Ethical Considerations:

The research protocol received ethical approval from the Udyaan Healthcare Institutional Ethics Committee (*Registration number ECR/1300/inst/UP/2019*). Participants provided informed consent after receiving comprehensive details about the study's objectives and procedures, in adherence to ICH-GCP standards and the Declaration of Helsinki.

Results

Out of the 7 clinics of Lucknow city, data of 352 patients (189 male and 163 female) with T2DM and MASLD were assessed. Baseline demographic details of study participants are mentioned in Table 1.

Table 1- Demographics of the study population (N = 352)

Variables	Mean ± Standard Deviation (SD)
Age (Years)	52.6±10.5
W.C. (cm)	101.3±9.7
BMI (Kg/m^2)	28.3±4.5
TG (mg/dL)	221.3±174.4
HDL (mg/dL)	44.9±9.7
TG:HDL	5.4±5.9
AST (U/L)	33.5±18.1
ALT (U/L)	38.9±30.0
ALB (g/dL)	4.4±0.4
PLT	189.2±66.6
HbA1c	8.0±1.8 %
FPG (mg/dL)	150.9±59.4
PPG (mg/dL)	217.6±86.0

(*W.C.- Waist circumference, HbA1c: Haemoglobin A1c; FPG: fasting plasma glucose; PPG: postprandial plasma glucose; BMI- Body Mass index, TG: triglycerides; HDL: high density lipids; AST-Aspartate transaminase, ALT- Alanine transaminase; ALB: Albumin; PLT: Platelet count*)

CAP score was found to be significantly correlated with BMI, Waist Circumference, FPG, PPG, and Serum Triglyceride. It showed a negative correlation with Serum HDL. LSM score was found to be significantly correlated with Waist Circumference, BMI, Liver enzymes ALT and AST but no significant correlation was seen with blood sugar levels, serum triglyceride, HDL levels, serum albumin, and platelet count (Table 2). Overall, it highlights the variability in fibrosis detection and prediction in MASLD patients depending on the method used, with significant proportions falling into both definite and indeterminate categories across different assessment tools (Figure 2).

Table 2- Pearson Correlation Coefficient of CAP & LSM compared with all parameters

	Pearson r (CAP)	95% confidence interval (CAP)	Pearson r (LSM)	95% confidence interval (LSM)	p(two-tailed)
Age	-0.08485	-0.1877 to 0.01986	0.005906	-0.09869 to 0.1104	0.1121
W.C.	0.4022	0.3030 to 0.4929	0.1590	0.1140 to	<0.0001

				0.3289	
BMI	0.4023	0.3047 to 0.4915	0.2710	0.1659 to 0.3721	<0.0001
TG	0.1465	0.04190 to 0.2480	-0.00059	-0.1105 to 0.1000	0.0062
HDL	-0.1621	-0.2627 to -0.05793	-0.1091	-0.3017 to -0.09998	0.0024
TG:HDL	0.1343	0.02946 to 0.2363	0.1198	0.01475 to 0.2223	0.0123
AST	0.07845	-0.02645 to 0.1816	0.1543	0.05044 to 0.2549	0.1424
AST	0.07802	-0.02688 to 0.1812	0.123	0.01859 to 0.2248	0.1446
ALB	0.06201	-0.04496 to 0.1676	-0.007940	-0.1448 to 0.06826	0.2556
PLT	-0.00687	-0.1116 to 0.09803	-0.07959	-0.1840 to 0.02431	0.8981
HBA1C	0.05092	-0.05390 to 0.1546	0.2234	0.1217 to 0.3205	0.3408
FPG	0.1306	0.02471 to 0.2335	0.04384	-0.06266 to 0.1494	0.0158
PPG	0.08168	-0.02320 to 0.1848	0.01967	-0.08519 to 0.1241	0.1267

(*W.C.- Waist circumference, HbA1c: Haemoglobin A1c; FPG: fasting plasma glucose; PPG: postprandial plasma glucose; BMI- Body Mass index, TG: triglycerides; HDL: high density lipids; AST-Aspartate transaminase, ALT- Alanine transaminase; ALB: Albumin; PLT: Platelet count, p value, probability value*)

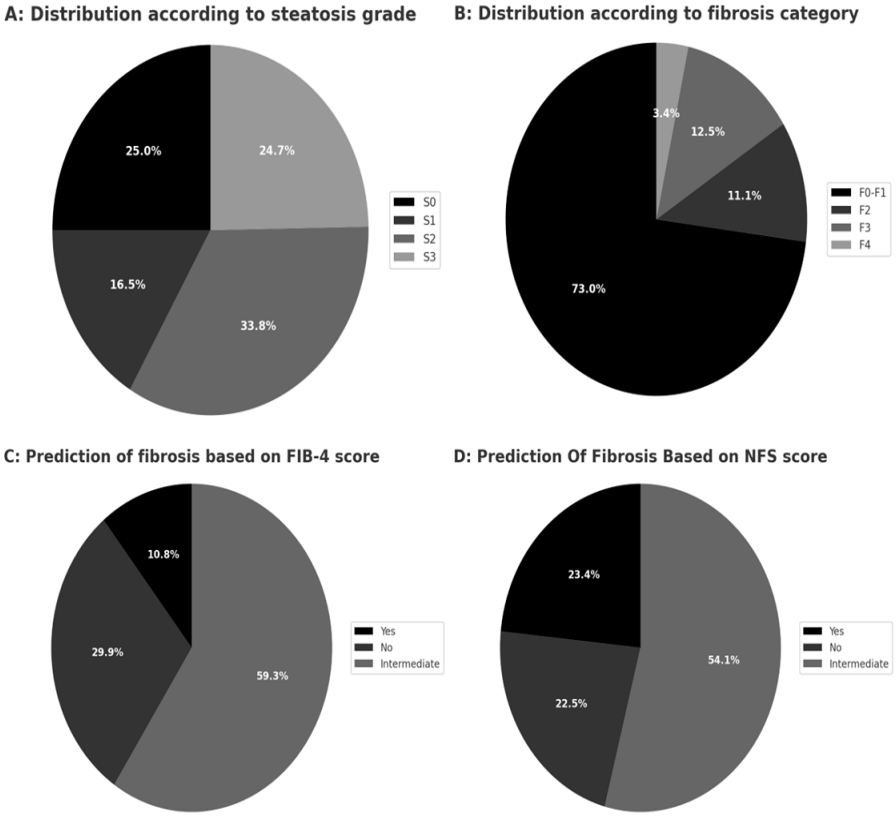

Figure 2- Distribution and prediction of fibrosis in patients with MASLD, evaluated using different scoring systems.

In our study, The CAP and FIB-4 score have no correlation, suggesting they measure different aspects of liver health or fibrosis. The FIB-4 score and NFS have a moderate positive correlation (r =

0.42), indicating that these scores are more related to each other compared to the relationships involving CAP (Figure 3a). Based on Spearman's formula, there was no significant correlation between the FIB-4 Score, and CAP Score. According to spearman correlation coefficient, there is a correlation, although a weak one, of LSM with FIB-4 (r=0.22). A very weak correlation (r = 0.13) was seen between LSM and the NFS. A moderate positive correlation of 0.42 between the FIB-4 score and NFS indicates a more substantial relationship, suggesting that as the FIB-4 score increases, the NFS tends to increase as well (Figure 3b).

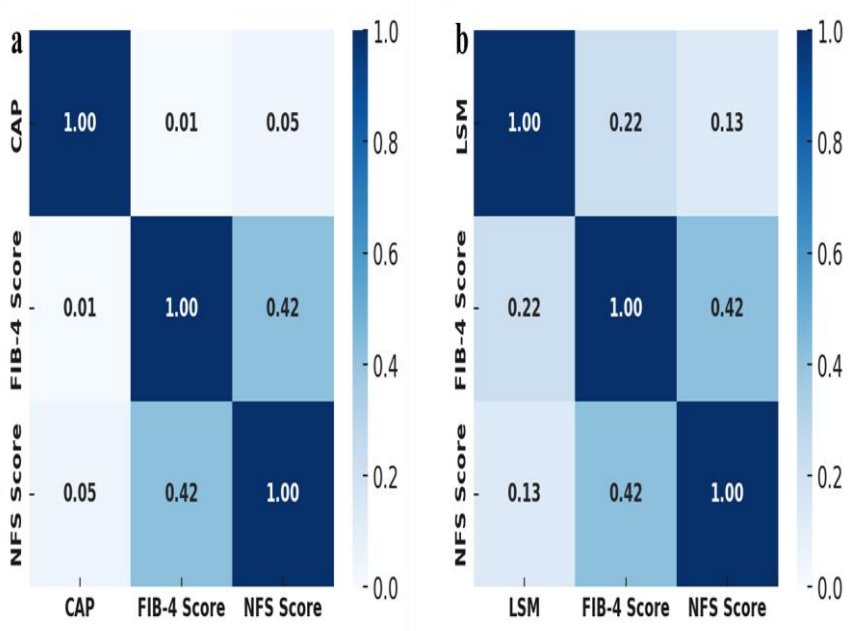

Figure 3- a) The figure is a correlation matrix that shows the relationship between CAP, FIB-4 score, and NFS. b) Corelation matrix here shows the comparison between LSM, FIB-4 score, and NFS.

Spearmen's coefficient was also used to understand relationship between LSM, FIB-4 and NFS (Table 3) The sensitivity of the FIB-4 scores to predict liver fibrosis is 49% with 95% CI (35.4 - 62.9), and the positive predictive value was 17% with 95% CI (10.8-26.9). The specificity of FIB-4 score was 75% with 95% CI (69.5 - 79.7), and negative predictive value was 93% with 95% CI (89.1 - 95.8).

Table 3- Spearman correlation analyses between LSM and two other scores: FIB-4 score and NFS score

Spearman correlation	**LSM vs. FIB-4 score**	**LSM vs. NFS**
R	0.2239	0.1345
95% confidence interval	0.1189 to 0.3240	0.02711 to 0.2388
p value	<0.0001	0.0117

(r, coefficient of co-relation, p <0.05 is significant)

The Area under the receiver operating characteristic (AUROC) shows that FIB-4 has higher sensitivity in cases of fibrosis of liver. The accuracy of FIB-4 score to use as screening test for liver fibrosis was 60.1% which was statistically significant as the p-value was 0.01. (Figure 4) The screening criterion of the FIB-4 score for liver fibrosis was >2.26.

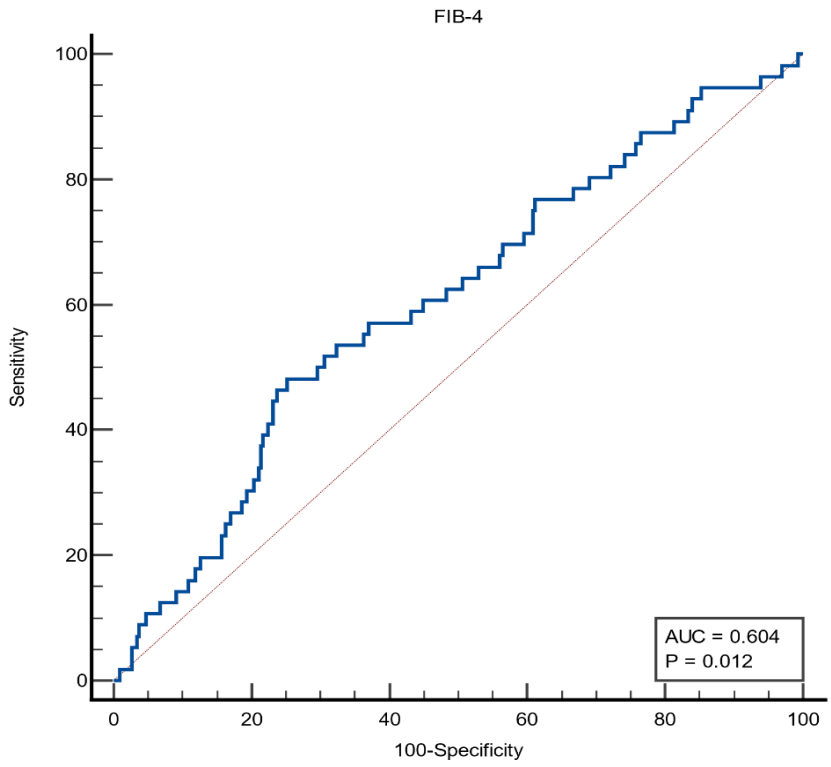

Figure 4-Area under the receiver operating characteristic (AUROC) curve shows the specificity as well as sensitivity of FIB-4 as a diagnostic as well as prognostic assessment method

Discussion

Most patients with asymptomatic liver disease are treated in primary care, where the condition often remains unnoticed. In this context, routine blood tests may become essential for identifying undetected cases. The European Association for the Study of the Liver-European Association for the Study of Diabetes-European Association for the Study of Obesity (EASL–EASD–EASO) Guidelines have emphasized the importance of screening for MASLD within the community and have called for validated studies on the cost-effectiveness of broad screening initiatives. This is due to the significant prognostic implications of MASLD progression to NASH, highlighting the necessity of identifying patients who are at risk [17]. EASL recommends using serum scores such as FIB-4 and VCTE measured LSM (FibroScan™) for assessing liver-related risk [14]. FIB-4 has demonstrated the ability to predict high-risk varices in patients with cirrhosis and forecast long-term survival in patients with hepatocellular carcinoma after hepatectomy. Thus, FIB-4 is crucial in primary healthcare for evaluating the progression and long-term outcomes of chronic viral hepatitis, MASLD, alcoholic liver disease (ALD), and autoimmune hepatitis (AIH) [18]. Our study revealed that the screening accuracy of FIB-4 was 60.1%, a result that was statistically significant with a p-value of approximately 0.01. FIB-4 demonstrates considerable potential for diagnosing liver fibrosis related MASLD, and it proved to be a useful predictor for both long-term and short-term outcomes in cases of T2DM patients.

In the present study, most participants exhibited either no fibrosis or mild fibrosis, with 72.9% classified as F0 and F1 combined, while 11.1% were F2, 12.5% were F3, and 3.4% were F4. These findings are consistent with the study by Ahmed et al. (2020), which used VCTE and non-invasive scores to assess hepatic fibrosis and steatosis in MASLD patients, finding that 80% were F0 and F1 combined, and 2.22% were F4. Our data also showed a positive correlation between the FIB-4 score and liver stiffness measured by VCTE ($r = 0.22$, $p < 0.001$) [16], which aligns with Fallatah et al. (2016) study that also found a significant positive correlation between liver stiffness measured by transient

elastography and FIB-4 results ($r = 0.50$, $p < 0.001$) [19]. Furthermore, Ahmed et al. (2020) compared six non-invasive liver fibrosis markers in 576 biopsy-proven MASLD patients and found that the FIB-4 score had a sensitivity and specificity of 90% and 64%, respectively, for diagnosing significant fibrosis, with a diagnostic accuracy of 87.1% (AUROC 0.871) [16]. Additionally, we found no statistically significant correlation between platelet count and liver stiffness measured by transient elastography ($r = -0.07$, $p = 0.147$), which differs from Fallatah et al. (2016) findings of a strong negative correlation between platelet count and liver stiffness.[19] Present research also identified a significant correlation between serum triglycerides (TG) and steatosis measured by CAP score ($r = 0.23$, $p < 0.001$). Kwok et al. (2016) similarly found that a CAP score of ≥ 222 dB/m was linked to higher TG levels in a study of 1,918 patients [20].

FIB-4 was also found to be associated with cardiovascular risk score systems in patients with HCV related cirrhosis or MASLD, showing higher scores among those with significant or advanced fibrosis compared to those with nil to moderate fibrosis. Thus, FIB-4 may be instrumental in the secondary prevention of MASLD in high-risk populations [21]. Additionally, we observed significant correlations between BMI and W.C with steatosis grades and values measured by CAP ($r = 0.27$, $r = 0.25$, respectively, $p < 0.001$). This is consistent with Dehnavi et al. (2018), who reported a strong correlation between BMI, WC, and steatosis grades and values ($p < 0.001$) [22], and Kwok et al., 2020, who found that a CAP score > 222 dB/m was linked to increased BMI and W.C [20]. Finally, our study revealed a significant correlation between T2DM, FPG and steatosis grades and values obtained by CAP ($r = 0.15$, $p = 0.0039$), consistent with Kwok et al. (2016) observation of a significant positive correlation between serum fasting blood glucose and steatosis, noting that 32-62% of diabetic patients had MASLD [20].

Conclusion

At present, there are no guidelines or policies recommending population-wide screening for MASLD. However, recent research indicates that screening among individuals who are obese or have diabetes could be cost-effective. In high-risk groups, especially within primary healthcare, the FIB-4 score might play a significant role in the primary prevention of cardiovascular diseases and secondary prevention of MASLD. By initiating screening and early interventions for these high-risk populations, there is potential to reduce liver related complications and mortality rates, which could also bring economic benefits.

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