

## Original Research Article

# Non-alcoholic fatty liver disease- correlation between shear wave elastography and nafld fibrosis score: a descriptive single centre study

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**Received:** 29 March 2022

**Revised:** 28 April 2022

**Accepted:** 30 April 2022

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## ABSTRACT

**Background:** Due to the global burden of obesity and type 2 diabetes, prevalence of NAFLD is now increasing, becoming one of the most common cause of chronic liver disease and liver transplantation both for end-stage liver disease and hepatocellular carcinoma. Although traditionally liver biopsy is gold standard for diagnosis of NAFLD, majority of patients can be non-invasively diagnosed with various tools like scoring systems (NAFLD fibrosis score, BARD score), ultrasound and MR elastographic techniques. The primary objective of this study was to assess the liver stiffness measurement by shear wave elastography and assess correlation between LSM by SWE and NAFLD fibrosis score in NAFLD patients.

**Methods:** This is a descriptive study comprising 75 patients with clinical suspicion of NAFLD, referred from Gastroenterology department from January 2020 to June 2021. All patients had undergone SWE, NAFLD fibrosis score calculated and results analyzed.

**Results:** Among the 75 patients studied, applying low cut off value of NAFLD fibrosis score (below -1.455), the presence of advanced fibrosis was excluded and by applying the high cut off point (>0.676) majority of subjects had advanced fibrosis. The NAFLD fibrosis score was correlated with E median values of liver stiffness measurement using Pearson correlation test and showed a moderate positive correlation ( $p=0.0001$ ,  $=0.685$ ) between both the variables.

**Conclusions:** Our study showed positive moderate correlation between NAFLD fibrosis score and LSM by 2D SWE. Multistep strategies using liver 2D SWE and NAFLD fibrosis score in combination can be used in the future to accurately diagnose or exclude the presence of advanced fibrosis in NAFLD patients.

**Keywords:** Non-alcoholic fatty liver disease, Shear wave elastography, NAFLD fibrosis score

## INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) is now an increasingly prevalent disease which is very often associated with type 2 DM and obesity. It is estimated that 25 % patients can develop NASH which can progress to cirrhosis.<sup>1</sup>

Approximately 20-30% individuals have non-alcoholic fatty liver disease and complications of NAFLD may become a factor for liver transplantation.<sup>2</sup>

NAFLD is a spectrum of clinicopathological entity progressing from simple steatosis to varying degrees of fibrosis with necroinflammation (NASH) to cirrhosis. It has a strong association with metabolic syndrome and is one of the leading cause of progression to chronic liver disease reaching epidemic proportions worldwide.<sup>3</sup>

Traditionally biopsy of the liver was used for assessment of fibrosis in liver disease patients, however it is invasive and is associated with multiple complications. Recently liver biopsy has been replaced by various non-invasive

tests which are incorporated into major guideline on NAFLD.<sup>4</sup>

Independent indicators of liver fibrosis are age, BMI, hyperglycaemia, albumin, platelet and AST/ALT ratio. A scoring system- NAFLD fibrosis score based on these 6 parameters helps in estimating and predicting the presence or absence of fibrosis in NAFLD. By applying the scoring system the number of liver biopsies could be decreased and thereby the complications associated with the procedure.<sup>5</sup>

Ultrasound can be used for screening and as a widely available non-invasive tool for diagnosing NAFLD with sonographic features. With clinical risk factors, ultrasound have high accuracy in identifying patients with NAFLD.<sup>6</sup>

Most intensively used method is ultrasound based elastography. Different elastography methods include strain imaging, transient elastography, point SWE and 2D-SWE. Among these 2D-SWE is the frequently used diagnostic tool in quantification of fibrosis. In 2D-SWE there is emission of multiple acoustic pulses which generates waves to cause tissue displacement and can sample large area in liver under B mode observation and a colour map of shear wave values can be obtained.<sup>7</sup>

Combination of laboratory and US elastography helps in early diagnosis of fibrosis in NAFLD patients. 2D SWE is significantly superior when compared to US in detecting fibrosis and cases of early cirrhosis.<sup>8</sup>

Often liver disease and fibrosis are unrecognised in patients, it is crucial for prompt diagnosis for early clinical management and lifestyle changes.

Ekstedt et al. recently confirmed that hepatic fibrosis stage is the strongest predictor for all-cause and disease-specific mortality in histologically confirmed NAFLD patients, who were followed-up for a mean period of 26.4 years.<sup>9</sup>

### **Non-invasive diagnosis of fibrosis**

#### *Clinical and laboratory markers*

Male sex, diabetes mellitus, obesity, Caucasian ethnicity, increased levels of aspartate transaminase and alanine aminotransferase are clinical predictors and risk factors for advanced fibrosis in NAFLD patients. However poor correlation is noted between ALT levels and NASH. AST is noted to be a better predictor when compared to ALT. In studies an AST/ALT ratio of >1 was found in association with advanced cases of fibrosis.<sup>10,11</sup>

#### *NAFLD fibrosis score*

Several scoring systems have been developed with purpose of identifying patients with possible risk of liver

fibrosis. Angulo et al validated the NAFLD fibrosis score (NFS) in a study of >700 patients compared with biopsy proven NAFLD. It was based on six routinely used clinical parameters.

The parameters used are age, presence of diabetes mellitus or impaired fasting blood glucose, BMI, platelet count, AST/ALT ratio and albumin levels.<sup>5</sup>

#### *NAFLD fibrosis score*

$$\begin{aligned} &= -1.675 + 0.037 - \text{age (years)} \\ &+ 0.094 - \text{BMI} \left( \frac{\text{kg}}{\text{m}^2} \right) \\ &+ 1.13 \times \frac{\text{IFG}}{\text{diabetes}} (\text{yes} = 1, \text{no} = 0) \\ &+ 0.99 \times \text{AST} \div \text{ALT ratio} \\ &- 0.013 \\ &\times \text{platelet count} (\times 109 \div 1) \\ &- 0.66 \times \text{albumin} \left( \frac{\text{g}}{\text{dl}} \right).^{12} \end{aligned}$$

According to Angulo et al, score of less than -1.455 has a low risk, relatively high negative predictive value to rule out case of advanced fibrosis and a score of more than 0.676 has a high risk for advanced fibrosis. However in patients those included in the indeterminate range i.e. between the above two values, need to undergo biopsy.<sup>5</sup>

#### *Other scoring systems*

##### *BARD score*

It is composed of 3 variables- AST/ALT ratio more than or equal to 0.8-2 points, BMI >28-1 point, presence of diabetes- 1 point.

The range of scoring system is 0-4 points. Harrison et al in a study concluded that the BARD score of 0 or 1 are high negative predictive value (96%) in advanced fibrosis.<sup>13</sup>

##### *FIB-4 score*

This scoring system is based on age, AST, ALT and platelet count. According to studies, FIB-4 score can rule out advanced fibrosis making liver biopsy avoidable in 62% patients when compared to 52% in NFS and 38% based on BARD system.<sup>12</sup>

#### *Ultrasound*

Abdominal US is now widely available and used 1st line tool for screening patients suspected with NAFLD.

#### *Characteristic sonographic features*

Presence of hepatic steatosis was characterised by increase in liver echogenicity, vascular blurring of hepatic and portal veins poor penetration of posterior

segment of right lobe of liver and blurring of diaphragm. Hepatic echoes was assessed compared to normal renal cortex.<sup>14</sup> With a steatosis of greater than 20% on biopsy, US features were able to predict NAFLD with a sensitivity of >90%. Lower levels of steatosis reduced the sensitivity. Hamaguchi et al developed a scoring system by which they were able to report similar sensitivities in biopsy proven NAFLD.<sup>15</sup>

### Elastography

Elastography techniques is an emerging technology to measure the stiffness and the mechanical properties in non-invasive way by measuring the velocity of the ultrasound waves which propagates through liver. As the fibrosis of liver increases, the stiffness increases making the waves to travel faster in it and slower in soft tissues.<sup>16</sup> Various types of elastography are classified on the basis of their source (static, quasistatic, dynamic), the duration of tissue deformation (continuous or transient) and the modality used (US or MRI), techniques have also been classified on basis of device type, wave generation methodology and reported parameters.<sup>17</sup>

### 2D - shear-wave elastography

Shear waves are generated as transverse waves when a directional force is being applied to tissue that causes deformation. Principle behind 2D SWE is that it produces acoustic radiation force in multiple focal zones. These shear waves are generated near the region of interest in liver parenchyma, numerous focal points generated simultaneously creates a conical shear wave front which sweeps image plane on either side of focal point.<sup>18</sup>

2D SWE images are displayed in colour coded maps superimposed on B mode images. The mean of the Young modulus in the region of interest is measured.

### Advantages

Multiple ROIs can be positioned on elastograms, reducing sampling variability which can occur with point SWE and 1D TE.

### Limitations

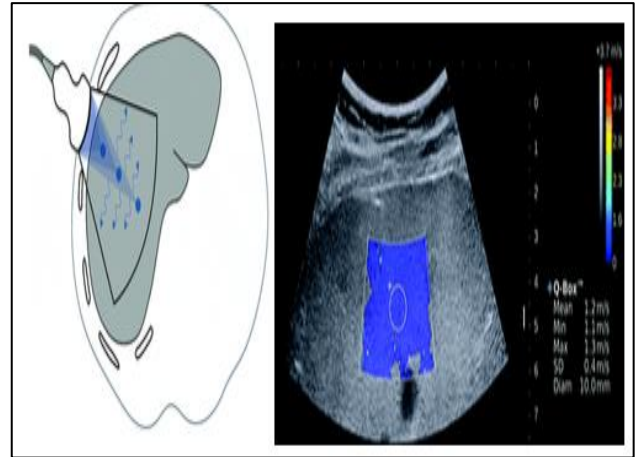
Restricted product availability.<sup>17</sup>

Liver stiffness is measured as the shear wave speed (m/s) or elasticity (kilopascals). All SWE devices measure the shear wave speed although in some shear wave speed can be converted to elasticity by using the formula.

$$E = 3\rho VS^2$$

Where E corresponds to the young modulus (kilopascals),  $\rho$ - tissue density ( $\text{g/m}^3$ ), Vs- shear wave velocity (m/s). Currently each vendor uses its own instructions, which raises the issue of standardization.<sup>19</sup>

GE healthcare and Philips healthcare have released commercial shear-wave elastography packages for their imaging systems. These systems use acoustic radiation force for generation of transient shear waves. Cut off values in various stages of fibrosis vary across ultrasound systems from different vendors.



**Figure 1: Probe location, direction of shear-wave propagation, source of shear-wave generation (blue arrows) and FOV. Also shown are companion images by elastography technique: 2D SWE.**

### MR elastography

MR elastography uses continuous waves. Recently MR elastography has been shown to have potential in detecting liver fibrosis, a technique which image the viscoelastic mechanical properties i.e. stiffness or elasticity of tissue. Liver becomes firm in fibrosis leading to changes in mechanical properties which can be measured by MRE. Number of studies have shown it to be accurate diagnostic tool.<sup>20</sup>

### Liver biopsy

Liver biopsy is traditionally the gold standard to confirm or exclude the diagnosis and determine the degree of liver damage for treatment and prognosis. However biopsy has various limitations. Performing biopsy on every patient with suspicion of NAFLD remains a controversy in daily practice and is not practical as a screening tool.

The primary objective of this study was to assess the liver stiffness measurement by shear wave elastography and assess correlation between LSM by SWE and NAFLD fibrosis score in NAFLD patients.

### METHODS

A descriptive study was carried out in the department of Radiodiagnosis at Amala institute of medical sciences, Thrissur for a period of 18 months (January 2020-June 2021). 75 subjects were included in this study with clinical suspicion of NAFLD. Shear wave elastography

was carried out and NAFLD fibrosis score was also calculated.

**Inclusion criteria**

Patients with clinically and sonologically suspected cases of NAFLD. Age group of study subjects was 25-65 years.

**Exclusion criteria**

Patients with other causes of chronic liver disease (HBV or HCV infection, hemochromatosis, autoimmune hepatitis etc), ascites, insufficient visualization of hepatic vasculature, IQR/Med >0.3.

After obtaining informed consent from patients for inclusion in the study, data was collected and LSM by shear wave elastography and NAFLD score was recorded based on a structured format.

**Equipment**

GE Healthcare LOGIQ S8 R3.

**Technique**

All patients fulfilling the inclusion and exclusion criteria was included.

**Liver stiffness measurement**

The patient was imaged in supine or slight (30°) left lateral decubitus position, with the right arm elevated above the head to open the intercostal spaces and improve the acoustic window to the liver.

**Table 1: Staging of liver fibrosis by 2D SWE.**

Liver fibrosis staging	Score	kPa
Normal - mild	F1	6.48- 6.60
Mild- moderate	F2	6.60- 8.07
Moderate - severe	F3	8.07- 9.31
Cirrhosis	F4	>9.31

The B mode image was optimised for best acoustic window. Any mass lesion, vessels and bile duct was avoided.

The probe was placed on skin surface after applying gel and measurements obtained 4-5 cm deep to the skin and within a minimum 1-2 cm of liver parenchyma.

The patient was coached in breathing (to stop breathing at the end of normal expiration or inspiration) and measurements taken in a neutral position. Measurements was taken and outcomes was communicated in kilopascals (kPa). IQR/M ratio is lesser than 30%.

**Interpretation**

*NAFLD fibrosis score*

It will be calculated using the following routinely measured parameters.

*Formula*

$$\begin{aligned}
 & -1.675 + 0.037 \times \text{age}(\text{years}) + 0.094 \times \text{BMI} \left( \frac{\text{kg}}{\text{m}^2} \right) \\
 & + 1.13 \times \frac{\text{IFG}}{\text{diabetes}} (\text{yes} = 1, \text{no} = 0) \\
 & + 0.99 \times \text{AST} \div \text{ALT ratio} \\
 & - 0.013 \times \text{platelet} (\times 109 \div 1) \\
 & - 0.66 \times \text{albumin} \times \text{g/dl}
 \end{aligned}$$

*Interpretation*

NAFLD score < -1.455 = F0-F2 = low risk

NAFLD score -1.455-0.675 = indeterminate score

NAFLD score >0.675 = F3-F4 = high risk

**Statistical analysis**

The data obtained was entered in Excel software and analysis performed using Statistical package for social sciences (SPSS) 23. Results on continuous measurements was presented on mean±SD and results on categorical measurements are present in number (%). Significance is assessed at 5% level. Normality of the data was tested and the comparison between LSM by SWE and NAFLD fibrosis score analysed by Pearson correlation.

**RESULTS**

In this prospective study conducted in the Department of Radiodiagnosis, Amala Institute of Medical Sciences over a period of 18 months, after assessment of the inclusion and exclusion criteria, 75 patients with clinical suspicion of NAFLD was studied.

In our study most of the cases were between 25 to 65 years of age, the mean age group of the patients was 45.893 (Table 2).

**Table 2: Mean age of patients.**

Age (years)	Min	Max	Mean	SD
	25	65	45.893	11.5403

Among the 75 patients included in the study 34 (45.3%) were female and 41 (54.7%) were male (Figure 2). BMI among the study population ranged from 20.1 to 41.5 kg/m<sup>2</sup>. The mean BMI of the group was 27.38 kg/m<sup>2</sup> (Figure 3).

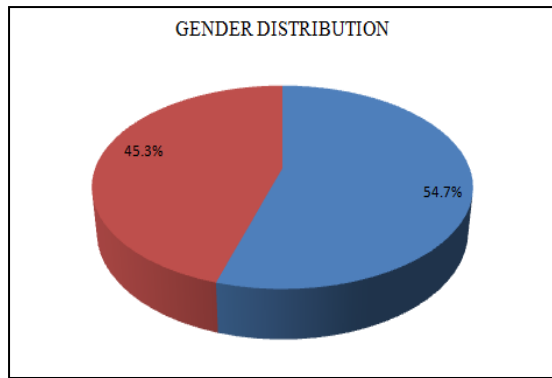


Figure 2: Gender distribution.

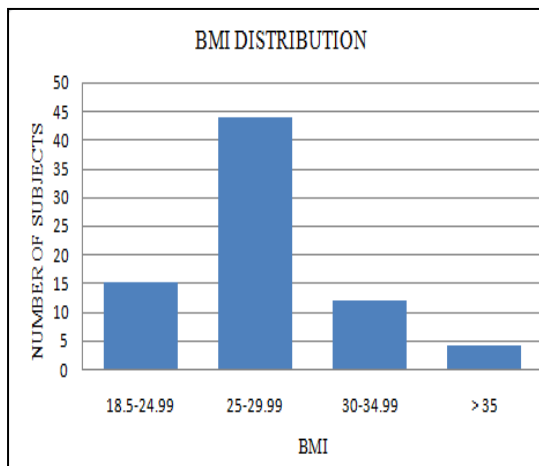


Figure 3: Frequency distribution of BMI.

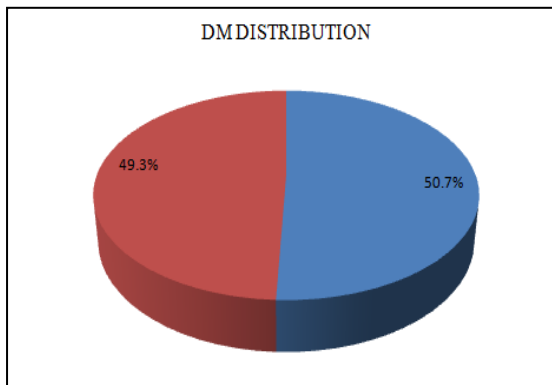


Figure 4: Frequency distribution of DM.

15 (20%) individuals among the study population had a BMI within the normal range, whereas 44 (58.7%) were categorized as overweight, 12 (16%) was categorized as obese and 4 (5.3%) as extremely obese.

In our study 50.7% patients were non diabetic and 49.3% diabetic (Figure 4). The percentages of patients with DM for each fibrosis stage by SWE (stage 0/1/2/3/4) were 31.03/50/57.6/66.66/66.66 (%) respectively. A weak positive correlation ( $p=0.023$ ,  $R=0.262$ ) was noted between BMI and liver fibrosis by 2D SWE. It was noted

the prevalence of diabetic patients increased with advanced stages of fibrosis. Correlation between AST and platelet values with liver fibrosis by 2D SWE was also assessed and showed a weak positive correlation ( $p=0.012$ ,  $R=0.288$ ) and a moderate negative correlation ( $p=0.0001$ ,  $R= -0.524$ ) respectively.

Table 3: Frequency distribution of NAFLD fibrosis score.

NAFLD FS	Frequency	Percentage
F0-F2	33	44.0
Indeterminant	35	46.7
F3-F4	7	9.3
Total	75	100.0

Table 4: Frequency distribution of stages of fibrosis by 2D SWE.

Stages	Frequency	Percentage
F0	29	38.7
F1	2	2.7
F2	26	34.7
F3	9	12.0
F4	9	12.0
Total	75	100.0

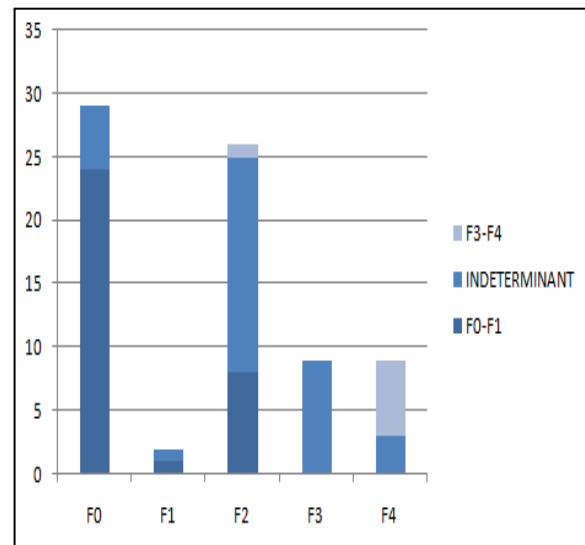
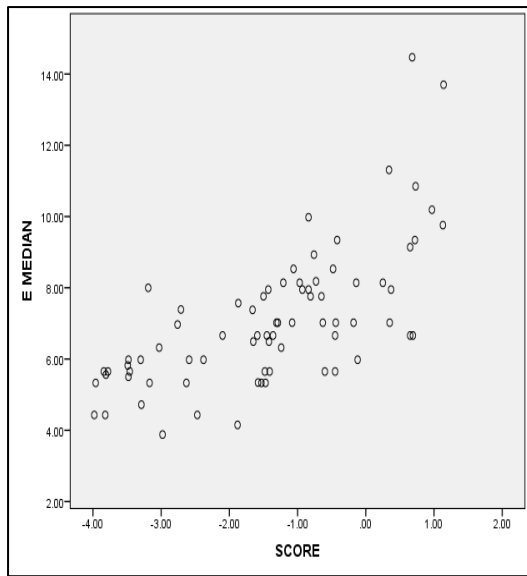


Figure 5: Frequency distribution of NAFLD fibrosis score based on stages of fibrosis by 2D SWE.

Among the study population according to NAFLD fibrosis score, 33 (44%) individuals belonged to low-risk category, whereas 35 (46.7%) were categorized as indeterminate and 7 (9.3%) was categorized as high-risk category (Table 3).

Among the study population according to SWE, 38.7% subjects belonged to F0 category followed by 34.5% to F2, 12% each in F 3 and F4 and 2.7 % in F1 category (Table 4).



**Figure 6: Relationship between NAFLD fibrosis score and liver stiffness measured by 2D SWE.**

Correlation coefficient calculated by Pearson’s correlation method showed a statistically significant linear relationship between these continuous variables (Liver stiffness and NAFLD fibrosis score). ‘p’ value was determined to be 0.0001 and Pearson correlation coefficient was 0.685, indicating a moderate positive correlation between NAFLD fibrosis score and liver stiffness measured by 2 D SWE (Figure 6).

**DISCUSSION**

This study was a descriptive study, done in non-alcoholic fatty liver disease patients. The study was aimed to assess the correlation of NAFLD fibrosis score obtained by the patients clinical and laboratory parameters and the fibrosis stage obtained by 2D SWE ultrasound elastography.

Of a total of 75 patients meeting the inclusion and exclusion criteria, the mean age group of the patients being 45.89, 34 (45.3%) were female and 41 (54.7%) were male.

**Table 5: Frequency distribution of NAFLD fibrosis score based on stages of fibrosis by 2D SWE.**

NAFLD FS	SWE					Total	0.0001
	F0	F1	F2	F3	F4		
F0-F2	24	1	8	0	0	33	
F3-F4	0	0	1	0	6	7	
Indeterminant	5	1	17	9	3	35	
<b>Total</b>	29	2	26	9	9	75	

The mean BMI in the study population was 27.38 kg/m<sup>2</sup> with majority of the patients falling in the overweight category and above. BMI was correlated with liver stiffness by 2D SWE using Pearson correlation test and showed a weak positive correlation between both the variables, suggesting that obesity is associated with advanced fibrosis. Younossi et al in a meta-analysis showed that obesity was noted in 51% of individuals those with NAFLD and about 82% of NASH patients, confirming that obese individuals make a significant proportion of NAFLD cases.<sup>21</sup>

In our study 50.7 % patients were non diabetic and 49.3% diabetic. The percentages of patients with DM for each fibrosis stage (stage 0/1/2/3/4) were 31.03/50/57.6/66.66/66.66 (%) respectively. It was noted that the prevalence of diabetes increased in advanced stages of fibrosis measured by 2D SWE. Takashi et al in a study stated that there is positive correlation between deterioration of glucose control and the fibrosis stage and this correlation is more prominent in case of females. Multivariate analysis identified age and DM as significant risk factors for advanced fibrosis.<sup>22</sup>

AST was correlated with liver stiffness by 2D SWE using Pearson correlation test and showed a weak positive correlation between both the variables, suggesting AST is

associated with advanced fibrosis. Angulo et al in a study concluded that AST is a better predictor for advanced fibrosis than ALT and an AST/ALT ratio of >1 was associated with advanced fibrosis.<sup>10</sup>

The correlation between platelet values and liver stiffness measurement was studied in our study and moderate negative correlation between the two variables was noted implying decreased values of platelet count in advanced stages of liver fibrosis. Masato et al in a study concluded that a linear decrease in the platelet count was noted with histologically increasing severity of hepatic fibrosis.<sup>23</sup> Fang et al in a study of 1303 participants showed that after 5 years of follow up the platelet counts markedly reduced at follow up in NAFLD group (p<0.0001) and provided evidence of significant association between risk of platelet reduction in patients with NAFLD.<sup>24</sup>

Among the study population according to NAFLD fibrosis score, 33 (44%) individuals belonged to low risk category, whereas 35 (46.7%) were categorized as indeterminate and 7 (9.3%) was categorized as high risk category and according to shear wave elastography 38.7% subjects belonged to F0 category followed by 34.5% to F2, 12 % each in F 3 and F4 and 2.7% in F1 category. The percentages of patients with low risk category in NAFLD fibrosis score for each fibrosis stage

(Stage 0/1/2/3/4) were 82.75/50/30.76/0/0 (%) respectively. Similarly for indeterminate and high risk category were 17.24/50/65.38/100/33.33 (%) and 0/0/5.8/0/66.66 (%) respectively.

It was noted in our study that by applying low cut off value from NAFLD fibrosis score (below -1.455), the presence of advanced fibrosis was excluded and by applying the high cut off point (>0.676) majority of subjects had advanced fibrosis. The NAFLD fibrosis score was correlated with E median values of liver stiffness measurement using Pearson correlation test and showed a moderate positive correlation ( $p=0.0001$ ,  $r=0.685$ ) between both the variables. Our study showed evidence that with increase of NAFLD fibrosis score, there is an increase in liver stiffness measurement by 2D SWE. Musso et al in a meta-analysis concluded the pooled AUROC, sensitivity, specificity of NAFLD fibrosis score in detection of NASH with fibrosis 0.85 (0.80-0.93), 0.9 (0.82-0.99), and 0.96 (0.94-0.99).<sup>25</sup>

Furlan et al in a study showed that 2D SWE has good diagnostic accuracy in detection of significant fibrosis with AUROC values of 0.80 and 0.89 in cases of advanced fibrosis.<sup>26</sup>

In another study by Lee et al the LSM values obtained with 2D SWE highly correlates with degree of hepatic fibrosis with the area under the ROC curve of liver stiffness values for stage F2 fibrosis or greater, stage F3 or greater, and stage F4 fibrosis 0.874 (95% confidence interval (CI): 0.794-0.930), 0.905 (95% CI: 0.832-0.954), and 0.894 (95% CI: 0.819-0.946), respectively.<sup>27</sup> Similarly several studies before has assessed the diagnostic performance of 2D SWE in liver stiffness measurement in biopsy proven cases of NAFLD.

### Limitations

However, our study included a relatively small number of subjects, which was a major limitations and liver biopsy was not done as a gold standard technique. Hence need for future research in large population is suggested.

### CONCLUSION

NAFLD has now become one of the most important cause of liver disease worldwide and can probably emerge as one of the leading cause of end-stage liver disease in the upcoming years. Both NAFLD fibrosis score as well as 2D SWE are validated tools for liver fibrosis assessment in NAFLD. 2D SWE is an emerging simple device integrated with US system with advantage of both ultrasound and liver stiffness measurement. Our study mainly assessed the correlation between the NAFLD fibrosis score and LSM by 2D SWE and it was shown to have moderate positive correlation as well as in low-risk individuals from NAFLD fibrosis score, advanced fibrosis was ruled out and in high risk

individuals majority of the patients were in advanced stages of fibrosis as measured by 2D SWE.

### Recommendations

Multistep strategies using liver 2D SWE and NAFLD fibrosis score in combination are widely available, easy to perform tools and can complement each other in the future to accurately diagnose or exclude the presence of advanced fibrosis in NAFLD patients. Thus can be used to significantly reduce the need for liver biopsy and its complications.

### ACKNOWLEDGEMENTS

Authors would like to thank the participants and all the faculty members in the Department of Radiodiagnosis, Amala Institute of Medical Sciences, Thrissur for their support and co-operation during the study.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** John A, Ambooken RP, Anil A. Non-alcoholic fatty liver disease – correlation between shear wave elastography and NAFLD fibrosis score: a descriptive single centre study *Int J Res Med Sci* 2022;10:1271-8.