Original Research Article

NAFLD Fibrosis Score or Ultrasonography a Better Practical Aid in Non-Alcoholic Fatty Liver Disease -A Hospital Based Comparative Study

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ABSTRACT

Background: Nonalcoholic fatty liver disease (NAFLD) is an emerging treat which may be taken as hepatic counterpart of metabolic syndrome. NAFLD is the earliest manifestation of metabolic syndrome and hence the need for devising the best screening tool for NAFLD that is cheap, simple and reliable. Here in this study we compare two important screening tools for NAFLD - ultrasonography and NAFLD fibrosis score.

Methods: This was a hospital based non-interventional observational study. After applying necessary inclusion and exclusion criteria, the study population was assessed in detail with set proforma and relevant investigations. The association of co-morbidities with ultrasonography and NAFLD fibrosis score was assessed. The agreement between ultrasonography and NAFLD fibrosis score in detecting hepatic fibrosis was assessed and reasons for discrepancy if any were also noted.

Results: Mean age of the study population of 377 was 43.8 years. Asymptomatic hepatomegaly was the single most common clinical sign. Significant association was noted between presence of comorbidities and severity of fibrosis in ultrasonography and NAFLD fibrosis score. Fibrosis score had fair agreement with ultrasound and the factors which produced significant fibrosis score in those detected to have mild fibrosis with ultrasound were increasing age and body mass index

Conclusions: NAFLD fibrosis score is a cheap screening tool applicable to majority of susceptible population. Even though score has many advantages over ultrasound the clinical applicability is still debatable due to its slight overestimation of fibrosis. NAFLD fibrosis score is excellent as a screening tool but doubtful as a diagnostic one.

Keywords: Non-alcoholic fatty liver, NAFLD fibrosis score, ultrasonography, metabolic syndrome, hepatomegaly

INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) is an umbrella term used to describe a wide spectrum of disease presentation observed in patients without history of significant ethanol, here in after termed alcohol, consumption. NAFLD was first described by Ludwig et al in 1980 as a liver biopsy with histological similarities to alcoholic liver disease but observed in patients without a history of extensive

[1] After the alcohol intake. initial description, NAFLD was thought to be a disease affecting only the obese or diabetic population. However in 1994 NAFLD was described in non-obese, non-diabetic population with normal lipid profiles making etiology and presentation of the disease all the more mysterious. ^[2] NAFLD is now considered as the most common liver disease and is treated as the hepatic counterpart of metabolic syndrome, which is

a lifestyle disease. ^[3] In 2003, Marchesini et al found out 88% of adult population with NAFLD had at least one feature of metabolic syndrome and nearly one-third of them had complete metabolic syndrome who were more prone for severe liver disease later in their life. ^[4] NAFLD is one of the earliest manifestations of metabolic syndrome and is a usual incidental finding picked up in routine ultrasonography during regular health check up or when done for some other cause. Considering NAFLD an early manifestation of metabolic syndrome, picking it up sufficiently early and advising life style modifications may prevent development of more severe diseases of the same spectrum like diabetes, hypertension dyslipidemia and among susceptible individuals.

The need to understand and diagnose NAFLD early was exemplified by National Family Health Survey which noticed obesity in 12.1% of Indian males and 16% of females. Obesity is the cornerstone of metabolic syndrome. Kerala, where this study is conducted is second only to Punjab in this list. In Kerala obesity was noted among 24.3% males and 34% females. ^[5] So Kerala is an ideal place to study about metabolic syndrome and related events. NAFLD fibrosis score is a noninvasive scoring system. It makes use of regularly checked variables like age, body mass index, diabetes status, liver enzymes, albumin value, and platelet count to assess hepatic fibrosis and is said to be comparable to liver biopsy which is the gold standard in assessing hepatic fibrosis.^[6,7] But liver biopsy being an invasive procedure should be done only if absolutely indicated and never as a screening test. Here in this study we are assessing the clinical applicability of NAFLD fibrosis score in Kerala population where obesity is extremely common and its comparability with ultrasonography, which is a very common and cheap method of assessing early hepatic steatosis.

Objectives of study: The objectives of this study were to assess the clinical profile of NAFLD patients briefly, clinical applicability of NAFLD fibrosis score and ultrasonography in NAFLD and its agreement with each other. Another objective was to assess the different variables influencing NAFLD fibrosis score and ultrasonography.

Study area: The study was a hospital based non-interventional observational cross sectional study conducted in MES Medical College Hospital, Perinthalmanna, Malappuram, Kerala. The dependant community of this medical college is a Muslim predominant one, where religious norms keep majority abstained from alcohol. However fat rich diet and sedentary lifestyle are very common here; both of which are attributed to early steatosis of liver.

Study period: Study period was taken as one year

Study population:

Inclusion criteria: All the people more than fifteen years of age presented to MES Medical College during the period of study with at least one of the three below mentioned conditions were included in the study irrespective of sex and locality. The conditions were 1) incidental detection of hepatomegaly during examination without any symptoms of the same, 2) incidental detection of raised liver enzymes aspartate and aminotransferase (AST) alanine aminotransferase (ALT) during investigation, 3) incidental detection of fatty liver in ultrasonography done for any other cause.

Exclusion criteria: The people excluded from study were 1) those with any amount of alcohol consumption, 2) those with history or positive serological evidence of acute or chronic hepatitis – infective or autoimmune, 3) those who were diagnosed to have hemochromatosis, Wilson's disease or any other chronic liver disease, 4) those with history of drug intake likely to alter liver enzymes like statins, 5) those who did not give consent.

MATERIALS AND METHODS

Sample size: After applying the above inclusion and exclusion criteria 517 patients were interviewed during the period of study of which 377 were included in the final analysis. Fifty eight patients did not give consent and eighty two were not willing for investigations.

Data collection technique and tools: Study was initiated after getting consent from scientific committee and ethical committee of the institute. Patients were introduced to study after getting an informed consent. They were evaluated by face to face interview sessions based on a statistically validated proforma that was giving emphasis to meticulous history, clinical investigations and relevant investigations. Interview and investigations were carried out on same day without any discomfort to the study population. Two important tools of the study were ultrasonography and NAFLD fibrosis score. In order to avoid inter-observer variability, ultrasonographies of all 377 patients were done by the same radiologist. Grading of fatty liver was done by visual analysis. Grade 1 was fatty liver with increased echogenicity alone, grade 2, fatty liver with increased echogenic liver obscuring the echogenic walls of portal venous branches and grade 3, fatty liver in diaphragmatic the outline which is obscured.^[8] In this study grade 1 is taken as mild fibrosis and grade 2 and 3 taken as significant fibrosis for all comparisons with NAFLD fibrosis score.

NAFLD fibrosis score = [-1.675] + [0.037 X]age in years] + [0.094 X body mass index] + [1.13 X diabetes status (yes 1, no 0)] + [0.99]X AST/ALT ratio] – [0.013 X platelets in 10^9 lakhs/L] – [0.66 X albumin in grams/dl]. Score of < -1.455 was unlikely to have fibrosis, -1.455 to 0.676 is indeterminate score, has mild fibrosis and > 0.676 is significant fibrosis. Age and diabetic status were availed through history, body mass index after examination (body weight in $meter)^2$). kilograms / (height in Investigations were done with well calibrated automated machines avoiding any bias. There are lots of websites and android applications now to provide NAFLD fibrosis score once we provide the variables. It is something we can do from bedside of a patient or from outpatient rooms. All NAFLD fibrosis score assessment in this study was done with online NAFLD calculator in gihep.com/calculators/ hepatology/NAFLD fibrosis score.

Statistical Methods:

The entire collected data was entered in Microsoft excel 2003 and analyzed with the help of appropriate statistical tools. Distribution of study population according to ultrasonography and NAFLD fibrosis score were calculated, association of metabolic syndrome with fibrosis score was identified. Associations of age, comorbidities and its duration with ultrasonography and NAFLD fibrosis score were calculated. Variables in NAFLD fibrosis score that significantly affect correlation with ultrasonography were assessed. The associations were assessed by performing Chi-square tests of which P value <0.05 were taken as significant. Cohen's Kappa coefficient was used to assess agreement between NAFLD fibrosis score and ultrasonography.

RESULTS

The mean age of study population was 43.8 years. But an alarming finding was 69.7% of study population was less than fifty years of age. In those people with NAFLD. patients (53.3%)201 were diabetic. 171 patients (45.4%) had 58.9% had dyslipidemia. hypertension, Another fascinating finding was emergence of full blown metabolic syndrome as a NAFLD patient's age increases. Among those NAFLD patients aged less than 25 years, none had diabetes but 80.7% of NAFLD patients above fifty years of age had diabetes. The same pattern was noted with hypertension, dyslipidemia and coronary artery disease. The increase in morbidities as age advances in NAFLD patients was found to be statistically significant as well. (Table 1)

Co-morbidities		Age in	years	Chi-square value	P value				
		15 – 25 years		26 - 50 years		More than 50 years			
		Count	Percent (%)	Count	Percent (%)	Count	Percent (%)		
Diabetes	No	37	100	117	51.8	22	19.3	78.96**	0.01
	Yes	0	0	109	48.2	92	80.7		
Hypertension	No	36	97.3	146	64.6	24	21.1	88.1**	0.01
	Yes	1	2.7	80	35.4	90	78.9		
Dyslipidemia	No	34	91.9	95	42	26	22.8	55.27**	0.01
	Yes	3	8.1	131	58	88	77.2		
Coronary Artery Disease	No	37	100	210	92.9	80	70.2	40.35**	0.01
	Yes	0	0	16	7.1	34	29.8		
			** 6	Statisticall	v significant va	hua			

Table 1: Association between age and co-morbidities in patients with NAFLD.

Statistically significant value

Family history of diabetes was present in 93.1% of study group. Family history of hypertension was detected in 92.3%, dyslipidemia in 89.9% and coronary artery disease in 61.3%. Among 377 NAFLD patients 76.9% were having metabolic syndrome showing the high prevalence of former in latter. The mean height of my study population was 164.7 centimeters and mean weight was 71 kilograms. Body mass index of 229 patients were between 26 and 30 kg/m². The mean body mass index of study population was 25.5 kg/m². Liver was palpable in 259 (68.7%) NAFLD patients, which was the single most important clinical feature present. Ferritin was elevated in 157 out of 198 (79.3%) males and 94 out of 179 (52.5%) females. Mean fasting blood sugar of the study group was 120.4 milligrams per deciliter and glycated hemoglobin was 6.4. Normal AST was detected in 275 patients (72.9%) and normal ALT was detected in 220 patients (58.4%). Albumin value was in all showing normal no marked abnormality in the synthetic function of liver and no evidence of chronicity of liver disease. Uric acid values were also normal in all.

Ultrasonography was done in all patients by the same radiologist and grade 1 fibrosis was taken as mild and grade 2 and grade 3 were taken as significant fibrosis. 166 patients (44%) had mild steatosis and 211 patients (56%) had significant steatosis. Significant association was found with increasing age and presence of comorbidities and severity of fibrosis detected through ultrasound. However no association was noticed with duration of comorbidities and steatosis in ultrasound. Any premorbidities irrespective of duration of illness, was producing almost same ratio significant of mild to fibrosis in ultrasound.(Table 2)

Table 2. Association between ultrasound findings and co-morbidities in patients with NAFLD

Co-morbidities		Ultrasound Findings				Chi-square value	P Value
		Mild fatty changes		Significant fatty changes			
		Count	Percent(%)	Count	Percent(%)		
Diabetes	No	104	59.1	72	40.9	30.38**	0.01
	Yes	62	30.8	139	69.2		
Hypertension	No	119	57.8	87	42.2	34.77**	0.01
	Yes	47	27.5	124	72.5		
Dyslipidemia	No	84	54.2	71	45.8	11.03**	0.01
	Yes	82	36.9	140	63.1		
Coronary Artery Disease	No	157	48.0	170	52.0	15.85**	0.01
	Yes	9	18.0	41	82.0		
Duration of Co-morbiditie	Duration of Co-morbidities		und findings	Chi-square value	P value		
		Mild fatty changes		Significant fatty changes			
		Count	Percent(%)	Count	Percent(%)		
Diabetes	<5 years	12	28.6	30	71.4	0.13	0.720
	>5 years	50	31.4	109	68.6		
Hypertension	<5 years	11	33.3	22	66.7	0.7	0.402
	>5 years	36	26.1	102	73.9		
Dyslipidemia	<5 years	20	47.6	22	52.4	2.54	0.111
	>5 years	62	34.4	118	65.6		
Coronary artery Disease	<5 years	2	18.2	9	81.8	0.35	0.839
	>5 years	2	13.3	13	86.7]	
		** 9	Statistically sig	nificant va	lue		

Fibrosis score was calculated in all 377 patients. 141 patients (37.4%) had score between -1.455 and 0.676 signifying mild fibrosis and 236 patients (62.6%) had score >0.676 suggesting significant fibrosis. Out of the patients with mild fibrosis score 55.8% had metabolic syndrome and 89.1% of patients with significant fibrosis score had metabolic syndrome. There was significant association between metabolic syndrome and fibrosis score (odds ratio of 6.49 and γ^2 value 52.87 with P value <0.01). So a patient with significant fibrosis score is a candidate for metabolic syndrome. Fibrosis score showed better association with co-morbidities which was more marked than ultrasound. Another advantage of fibrosis score over ultrasound was it showed association with duration of comorbidities as well. So with significant NAFLD fibrosis score, there is a higher chance of longer duration of co-morbidities, may be undetected previously, which we cannot commit with ultrasound examination. (Table 3)

Table 3: Association b	etween NAFLD fibrosis score and co-morbidi	ties in NAFLD

Co-morbidities		NAFLD fibrosis score				Chi-square value	P value
		Mild score		Significant score			
		Count	Percent(%)	Count	Percent(%)		
Diabetes	No	133	75.6	43	24.4	205.4**	0.01
	Yes	8	4.0	193	96.0		
Hypertension	No	136	66.0	70	34.0	158.88**	0.01
	Yes	5	2.9	166	97.1		
Dyslipidemia	No	100	64.5	55	35.5	82.66**	0.01
	Yes	41	18.5	181	81.5		
Coronary artery disease	No	138	42.2	189	57.8	24.28**	0.01
		3	6.0	47	94.0		
Duration of co-morbiditie	Duration of co-morbidities) fibrosis score	Chi-square value	P value		
		Mild score		Significant score		_	
		Count	Percent(%)	Count	Percent(%)		
Diabetes	<5 years	6	14.3	36	85.7	14.76**	0.01
	>5 years	2	1.3	157	98.7		
Hypertension	<5 years	4	12.1	29	87.9	12.19**	0.01
	>5 years	1	0.7	137	99.3		
Dyslipidemia	>5 years <5 years	1 21	0.7 50.0	137 21	99.3 50.0	34.2**	0.01
Dyslipidemia	>5 years <5 years >5 years	1 21 20	0.7 50.0 11.1	137 21 160	99.3 50.0 88.9	34.2**	0.01
Dyslipidemia Coronary artery disease	<pre>>5 years <5 years >5 years <5 years <5 years</pre>	1 21 20 0	0.7 50.0 11.1 0.0	137 21 160 11	99.3 50.0 88.9 100.0	34.2 ^{**} 2.28	0.01

** Statistically significant value

The Cohen's Kappa coefficient between NAFLD fibrosis score and ultrasonography was 0.35 which signified fair agreement. (Table 4)

Table 4: Agreement between ultrasound and NAFLD fibrosis score in assessing NAFLD

NAFLD fibrosis	Ultrasound fin	Total	
score	Mild fibrosis	Significant fibrosis	
Mild score	47	94	141
Significant score	164	72	236
Total	211	166	377

Kappa = 0.35, P = 0.01 [Fair agreement]

A comparison was made between fibrosis score and ultrasound findings. Out of 166

patients who were diagnosed to have mild fibrosis by ultrasound, 72 patients (43.3%) had significant NAFLD fibrosis score. It was found out as age increases percentage of those with significant NAFLD fibrosis score increases even if ultrasonography revealed mild fibrosis. Body mass index also had a very strong association with significant NAFLD fibrosis score. Albumin, platelets and diabetic status didn't have any correlation with significant NAFLD fibrosis score. (Table 5)

Age in years	NAFLE) fibrosis score	Chi-square value	P value		
	Mild score				Significant score	
	Count	Percent(%)	Count	Percent(%)		
<25	25	26.6	0	0.0	42.21**	0.01
25 - 50	65	69.1	46	63.9		
>50	4	4.3	26	36.1		
Body mass index in kg/m ²	NAFLE) fibrosis score	Chi-square value	P value		
	Mild score		Significant score			
	Count	Percent(%)	Count	Percent(%)		
<25	58	61.7	26	36.1	10.68**	0.01
>25	36	38.3	46	63.9		
Albumin in g/dl	NAFLE	fibrosis score	Chi-square value	P value		
	Mild score		Significant score			
	Count	Percent(%)	Count	Percent(%)]	
<3.5	5	5.3	9	12.5	2.72	0.099

94.7

SD

0.9

1.1

5 89

Those with thrombocytopenia (platelet count <1.5 lakhs/cumm)

Mean

2.4

2.3

Table 5: Association of NAFLD fibrosis score and variables in those patients who were reported to have mild fatty liver in ultrasou

72 Statistically significant value

63

Count 94

87.5

T value

0.52

P value

0.604

DISCUSSION

>3.5

Mild score

NAFLD fibrosis score

Significant fibrosis

The mean age group study population was 43.8 years. Various Indian studies are showing similar results whereas fatty liver disease is a disease affecting predominantly older age group in Western countries. ^[9,10] The dietary habits and lifestyle may be producing an early onset of fibrosis in Asian population. Even though almost all studies have showed high correlation between co-morbidities like diabetes, hypertension, dyslipidemia and coronary artery diseases, this study was an exception. ^[11,12] Diabetes, hypertension, dyslipidemia, coronary artery disease were detected in only 53.3%, 45.4%, 58.9% and 13.3% respectively in this study group. Relatively younger age group of the study population may be the cause for the same. Among those patients with fatty liver above 50 years of age, 80.7% had diabetes, 78.9% had hypertension, 77.2% had dyslipidemia and 29.8% had coronary artery disease. In those patients less than 25 years of age, fibrosis of liver was detected even with no associated co-morbidities. It may be taken in such a way that NAFLD is presumably manifestation the first of metabolic syndrome in a susceptible individual. So if we detect early fibrosis and intervene at the right time with dietary and lifestyle modifications, we may be able to prevent development of more serious counterparts of metabolic syndrome. 76.9% of the study population satisfied criteria for metabolic syndrome. In a large community based study conducted by Marchesini et al it was found that 88% of adult patients with NAFLD had atleast one feature of metabolic syndrome with one third of them satisfying complete criteria for metabolic syndrome. All those one third who satisfied criteria for syndrome very metabolic had severe fibrosis than the rest.

Out of 377 patients studied, 229 had their body mass index between 26 and 30 kg/m^2 . Body mass index more than 25 was suggested as a significant predictor for liver fibrosis. ^[13] Similar study conducted by Amarapurkar identified age more than 40, male gender, central obesity, body mass index more than 25, raised fasting blood sugar and raised liver enzymes as risk factors for liver steatosis. ^[14] Asymptomatic hepatomegaly was the most common clinical finding which was present in 259 patients. Only out of 377 periodic assessment will reveal fatty liver as it has a very benign clinical course.

Among the 377 patients, 72.9% had normal aspartate aminotransferase and 58.4% had normal alanine aminotransferase. Albumin values were also normal in majority patients. Similar findings were observed in study conducted by Yano et al where sensitivity of aminotransferases to

detect fatty liver was 35.7% which was even inferior to body mass index. ^[15] Liver enzymes can be normal in those with any given histological stage of NAFLD. ^[16] So the presence of normal or near normal aminotransferases does not exclude the possibility of underlying liver fibrosis and hence lies the significance of ultrasound and NAFLD fibrosis score in young asymptomatic overweight persons even without any co-morbidities and normal liver function tests.

Ultrasonography revealed mild fatty changes in 166 (44%) and significant fatty changes in 211 (56%). There was association with increasing age as more significant fibrosis was picked up with increasing age. There was also significant association between fatty liver picked up in ultrasound and presence or absence of comorbidities. However the duration of comorbidities were not influencing the ultrasound yield. Diabetes whether present for 1 year or 20 years effected the same fatty changes. The same was also noticed by Graif et al while he was assessing the utility of radiological imaging in NAFLD.^[17]

NAFLD fibrosis score was <0.676 in 141 patients (37.4%) and significant score was obtained in 236 patents (62.6%). There was marked association between presence of co-morbidities and the significance was even more than that for ultrasonography. Another interesting observation was with significant NAFLD fibrosis score we could comment on the duration of co-morbidities. With a significant fibrosis score there is a statistically proven high chance for longer duration of associated co-morbidities. The study has brought out fair agreement between fibrosis score and ultrasound. But the question to answer is whether fibrosis score can substitute ultrasonography in detecting NAFLD. There are a few definite advantages for fibrosis score. NAFLD fibrosis score not only gives valuable clues regarding duration of co-morbidities, it also has no inter-observer variability as in ultrasound as the former has a set formula and unique way of calculation irrespective of the examiner. Most of NAFLD patients are obese or overweight and abdominal fat tissue decreases visibility in ultrasound. Fibrosis score can be easily applied in such group of patients. Fibrosis score is a less time consuming process as there are dedicated android applications and websites for calculating the same. It is very much cost effective as it can be done with routine investigation variables. Technical expertise as that for ultrasound is not needed for assessing fibrosis with score which is another advantage.

Out of 166 patients diagnosed to have mild fatty liver by ultrasound, 72 had significant fibrosis score. These 166 patients were further assessed to know the values that may be causing the rise in fibrosis score. The variables in NAFLD fibrosis score were age, diabetic status, body mass index, platelet, aminotransferases and albumin values. It was found age and body mass index are the two factors that increase the NAFLD fibrosis score even in those with mild fatty liver changes in ultrasound. The effect of diabetes on the score was brought out by Qureshi et al in 2008.^[7] There is a chance of increased score with increasing age and body mass index also according to this study. Platelet, albumin and aminotransferase values were not significant factors in creating this difference between ultrasound and fibrosis score. As discussed previously increasing body mass index may be dampening visibility in ultrasound causing interpretation as mild fatty liver.

CONCLUSION

Nonalcoholic liver disease (NAFLD) hepatic counterpart of metabolic is syndrome. Asian studies including this show affected population comprising an predominantly younger patients. In those patients above fifty years of age there is significant occurrence of diabetes, hypertension and dyslipidemia. Most clinical presentation common was asymptomatic hepatomegaly. Majority had normal liver function tests. There was

significant association for ultrasound findings and associated co-morbidities. NAFLD fibrosis score was a novel method to assess fibrosis score based on a set formula and easily available variables. It is cost effective, less time consuming, needs no technical expertise, carries no interobserver variability and can be easily applied to obese as opposed to ultrasound. NAFLD fibrosis score shows comparable agreement to ultrasound and in addition gives clues regarding duration of comorbidities also. Age and increasing body mass index was seen to give a significant NAFLD fibrosis score in those with mild fatty changes in ultrasound. To conclude, NAFLD fibrosis score is superior to ultrasonography in various aspects including screening of susceptible population and early detection of fatty liver. But its clinical applicability is still debatable in view of slight over diagnosis of the extent of fibrosis and demonstration of significant fibrosis as age advances. So in short, NAFLD fibrosis score, an excellent screening tool is a doubtful diagnostic tool.

Recommendations:

High index of clinical suspicion is needed to detect NAFLD in its early stage. Fatty liver may be taken as the earliest manifestation of metabolic syndrome and diet and lifestyle modifications at right time may prevent occurrence of frank metabolic syndrome. Tests should be devised with more sensitivity and specificity to detect fatty changes as the prevalence of the same is rising alarmingly. Use of NAFLD fibrosis score may be encouraged as it is found comparable to ultrasound and can be applied in resource limited settings by a person without technical expertise needed for the later.

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