

Role of Fibroscan (Ultrasound Elastography) As a Non-Invasive Tool for Assessment of Fibrosis in Chronic Liver Diseases

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Abstract: The majority of chronic liver diseases are characterised histologically by liver fibrosis, which can advance to cirrhosis, liver failure, and predisposes to hepatocellular carcinoma. For decision-making, risk assessment, and prognosis of liver cirrhosis, accurate diagnosis is essential. The gold standard for evaluating liver fibrosis is liver biopsy, which is invasive, expensive, and unsuitable for surveillance and therapy response monitoring. Ultrasound Elastography (FIBROSCAN) offers a noninvasive, objective and quantitative alternative to liver biopsy.

OBJECTIVES: The aim of this study was to determine and review the comparative advantages and limitations of ultrasound elastography over liver biopsy.

MATERIALS & METHODS: The study was conducted at Department of Radio-Diagnosis, Medical College Kolkata. A total of 58 patients with chronic liver disease were examined with ultrasound elastography. The study was conducted from 1st August 2021 to 31st January 2022. Histopathologic diagnosis obtained from Liver biopsy were used as reference standards. Statistical analysis included Cohen's kappa K , sensitivity, specificity, and positive and negative predictive values.

RESULTS: A total of 58 patients were included with a mean age of 42.27 years (range 30-60 years). On histopathological evaluation, 6 (10.34%) cases have cirrhosis, 28 (81.3%) have advanced Fibrosis, 12 cases have significant-mild fibrosis and 4 cases have no fibrosis. The Fibroscan has higher sensitivity and specificity for identifying cirrhosis than mild to moderate fibrosis (F4: Sensitivity 0.92 and specificity 0.94; F2-F3 Sensitivity 0.82 and specificity 0.85).

CONCLUSION: The easy availability of Ultrasound Elastography provides an alternative to the use of liver biopsy in routine diagnostic assessment and follow up of significant fibrosis in the diagnosis, treatment and management of chronic liver disease patients.

Key word: Liver fibrosis, Ultrasound Elastography (UE), Transient Elastography (TE), Acoustic Radiation Force Impulse (ARFI), Shear Wave Elastography (SWE).

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I. Introduction

Liver fibrosis is a form of scarring that results from repeated liver injury and is a common pathologic in most forms of chronic liver diseases. Fibrosis can progress to cirrhosis, a severe stage reflecting years of cumulative damage and the most important risk factor for developing Hepatocellular carcinoma (HCC) and liver failure. Histology is the clinical reference standard for assessing liver fibrosis. Histopathologic diagnosis relies on detecting and characterising excessive extracellular matrix deposition within liver parenchyma.

Commonly used scoring systems for hepatitis B virus (HBV) and hepatitis C virus (HCV) infections are METAVIR Scoring and BRUNT Criteria for nonalcoholic steatohepatitis (NASH), into ORDINAL SCORING from 0 to 4, 0-no fibrosis, 1-mild fibrosis, 2-significant fibrosis, 3-advanced fibrosis and 4-cirrhosis. The main advantage of histology is direct evaluation of liver collagen and assessment of microscopic lesions other than fibrosis. However, main limitations of histology are liver biopsy which is invasive, costly, intra-observer and inter-observer variability, sampling errors and low patient acceptance. The liver tissue sample obtained for liver biopsy comprises only around 1/50,000th of the entire liver, which may not reflect the condition of the entire liver.

These limitations prompted searches for alternative noninvasive methods to assess liver fibrosis. In last decade elastography has emerged as a Quantitative imaging approach to noninvasively assess liver fibrosis. Elastography can be performed with Ultrasound or Magnetic resonance imaging.

BASIC CONCEPTS:

Elastography measures tissue stiffness that increases with higher fibrosis stages of liver. Many other factors also influence liver stiffness like inflammation,blood flow,portal pressure,hepatic-venous congestion and cholestasis.

Thus liver stiffness may serve as a proxy for liver fibrosis. Stiffness describes a tissue’s ability to resist deformation(strain) in response to an applied force(stress) and may be expressed as the ratio of stress/strain.

The quantitative elastography techniques involves the following steps:

- 1.Shear wave induction in tissue
2. Visualisation and analysis of shear wave propagation
- 3.Conversion of data into an estimate of tissue stiffness.

The stiffness related quantitative parameters are reported by Ratios of stress/strain known as moduli in units of Kilopascals(Kpa) or shear wave speed in meters per second(m/s). The common moduli reported are Young`s modulus, a measure of mechanical resistance to an axially applied stress.

There are 4 methods to assess the liver stiffness,

1. Vibration controlled Transient Elastography (VCTE)
2. Point Shear Wave Elastography (pSWE)
3. 2 Dimensional Shear Wave Elastography(2D SWE)
4. Magnetic Resonance Elastography (MRE)

Table1;Comparison between different techniques;

MODALITY	VCTE	pSWE	2D SWE	MRE
Accuracy Cirrhosis(stage4)	excellent	excellent	excellent	excellent
Stage2 or >	good	Good may be better than VCTE	Good may be better than VCTE	EXCELLENT
Stage1or >	POOR	POOR-FAIR	FAIR	GOOD
CHALLENGES	Obesity, Inflammation, Ascites, No visual guidance	Obesity, inflammation	Obesity, inflammation	Iron, Access, MR contraindications
Practical Advantages	Point of care access, Rapid output, Well validated, Optional quantitative assessment of fat	Access, Visual guidance, Simultaneous Ultrasonography	Access, Visual guidance, Simultaneous Ultrasonography	Low technical failure rates, Simultaneous Mr examination, Optional quantitative assessment of other MR biomarkers
Size of liver sampled	~3cm	~1cm	Variable sampled volume typically> 20cm	>250cm , Upto 1/3 of the liver volume
Anatomic imaging	none	Clinical US Exam	Clinical US Exam	Clinical MRI exam
Training required for operator	A single session	Experience with clinical US imaging plus some additional training	Experience with clinical US imaging plus some additional training	Experience with MRI plus some additional training
Training required for analyst	Not applicable	Not applicable	Not applicable	Training in ROI placement required

II. Materials & Methods :

Patients:

The study was conducted at Department of Radio-Diagnosis, Medical College Kolkata. A total of 58 patients with chronic liver disease were examined with B-mode sonography and subsequently with elastography. The study was conducted from 1st August 2021 to 31st January 2022. Patients mean age was 42.27years, ranging from 30 years to 60years.

Study design:

In each patient shear wave elastography was done with LOGIQ P9 GE Usg machine using 4-5 Hz frequency Curvilinear probe. Patient position; lying in supine position with the right arm on maximum abduction & breath holding. First scanning of right lobe of liver with B-mode was done in a region encompassing the 6th,7th and 8th intercostal spaces between anterior axillary and mid clavicular line, probe

holding perpendicular to liver capsule surface , avoiding ribs shadow and with minimum skin to liver capsule distance.. An area of liver tissue was selected 2 cm deep to liver capsule without major vessels or ducts, then SWE mode was on and a large ROI was scanned. Total 12 readings were taken keeping minimum area of 1cm of each circle. Readings of MEDIAN, Interquarantile Ratio(IQR) and IQR/Med ratio were taken. To increase the accuracy of results IQR/Med ratio was kept less than 30%.

Inclusion Criteria:

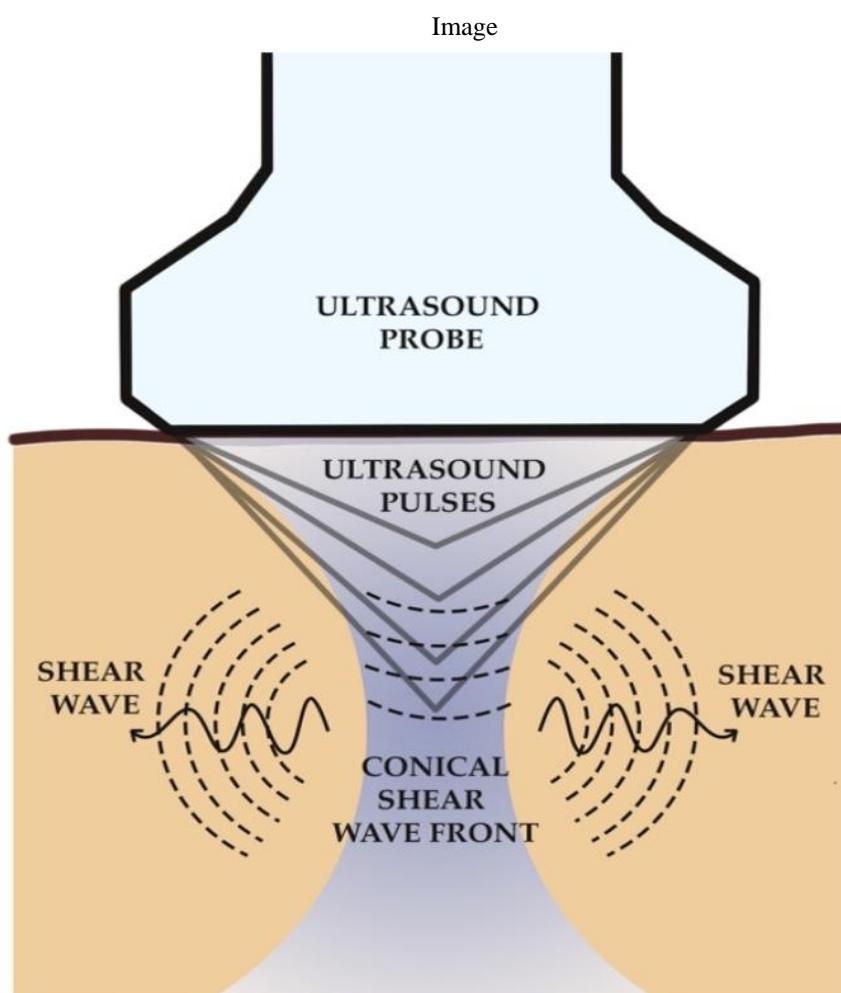
1. Patients with chronic liver disease .
2. Patients with Alanine aminotransferase(ALT)<2 times the upper normal limit.
3. Patients with informed consent for examination and willing for BIOPSY.

Exclusion Criteria:

1. Patients in acute inflammatory condition.
2. Patients not willing for BIOPSY.
3. Uncooperative patients.

Ethical Consideration:

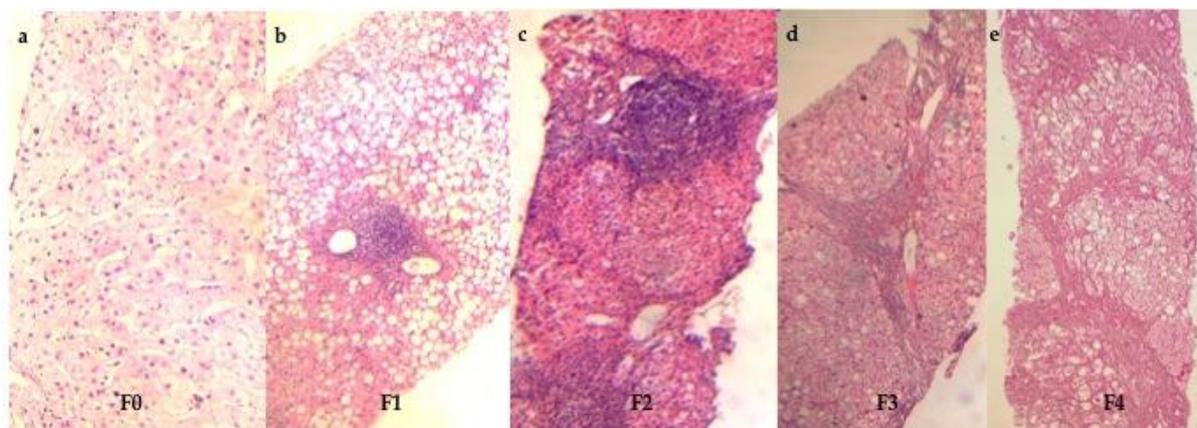
The study was conducted after getting approval from Institutional Ethics Committee and other authority. Informed consent was taken from all participants





Liver Fibrosis Staging	METAVIR SCORE	kPa	m/s
Normal	F0	2.0-4.5	0.81-1.22
Normal-Mild	F0-F1	4.5- 5.7	1.22-1.37
Mild- Moderate	F2-F3	5.7-12.0	1.37-2.00
Moderate - Severe	F3-F4	12.0-21.0+	2.00-2.64+

Table2; METAVIR SCORE



Fig; Progression of fibrosis from periportal fibrosis to cirrhosis according to the Metavir scoring system shown through photomicrographs (original magnification, ×10; Hematoxylin and Eosin stains) of histologic sections from liver biopsy specimens. (a) No fibrosis (stage F0). (b) Portal and periportal fibrosis only (stage F1). (c) Periportal fibrosis with few septa (stage F2). (d) Septal fibrosis and bridging without cirrhosis (stage F3). (e) Cirrhosis (stage F4) which appears as nodules of liver parenchyma separated by thick fibrous bands.

III. Results :

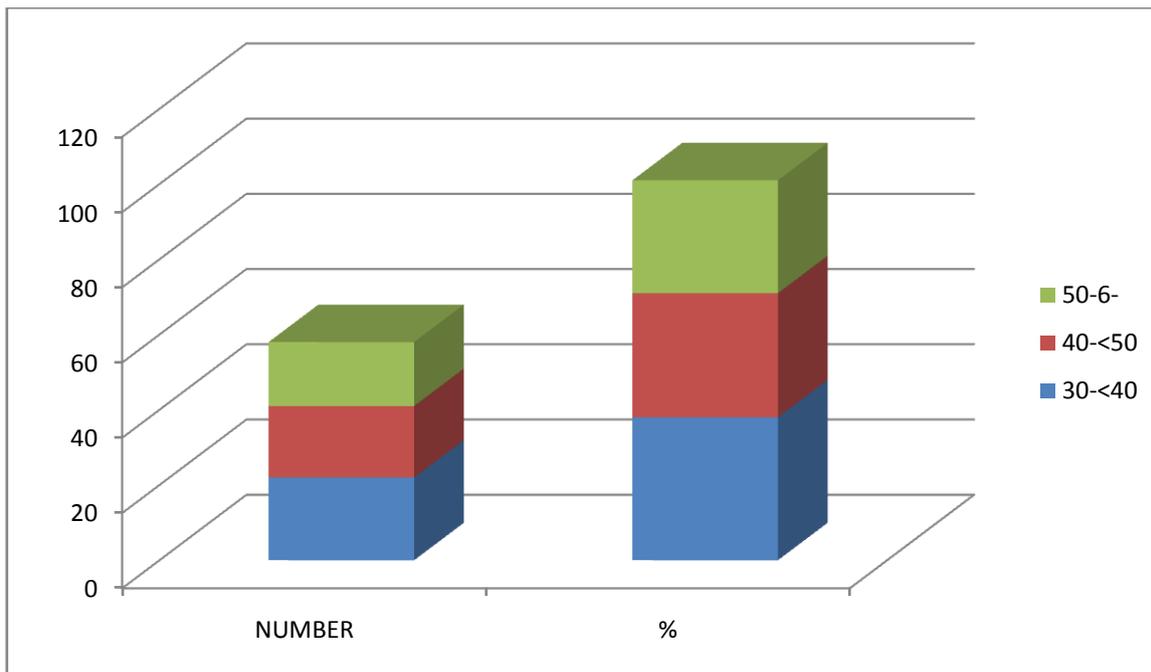
This is a Tertiary Care Hospital based study. All the studied patients with chronic liver disease were admitted in the medicine or gastroenterology department & were referred to radiology department for assessment of fibrosis.

Further results were corroborated with the pathological findings of biopsy reports.

This study included 58 patients with Chronic liver disease. Their ages ranged from 30 years to 60 years with a mean age of 42.27 years (table 1 and figure 2).

Age in years	number	percentage
30-<40	22	38%
40-<50	19	33%
50-60	17	30%
Max-min	30-60	
Mean+-SD	42.27	
Median		

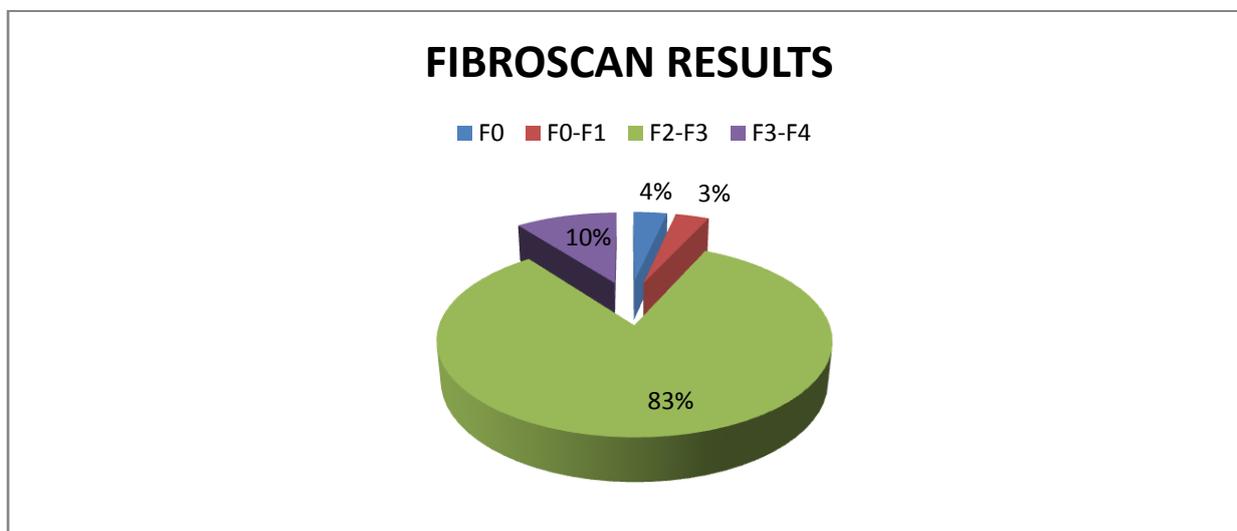
Table 1: Distribution of the studied cases according to age



Bar Diagram; Distribution of the studied cases according to age & percentage

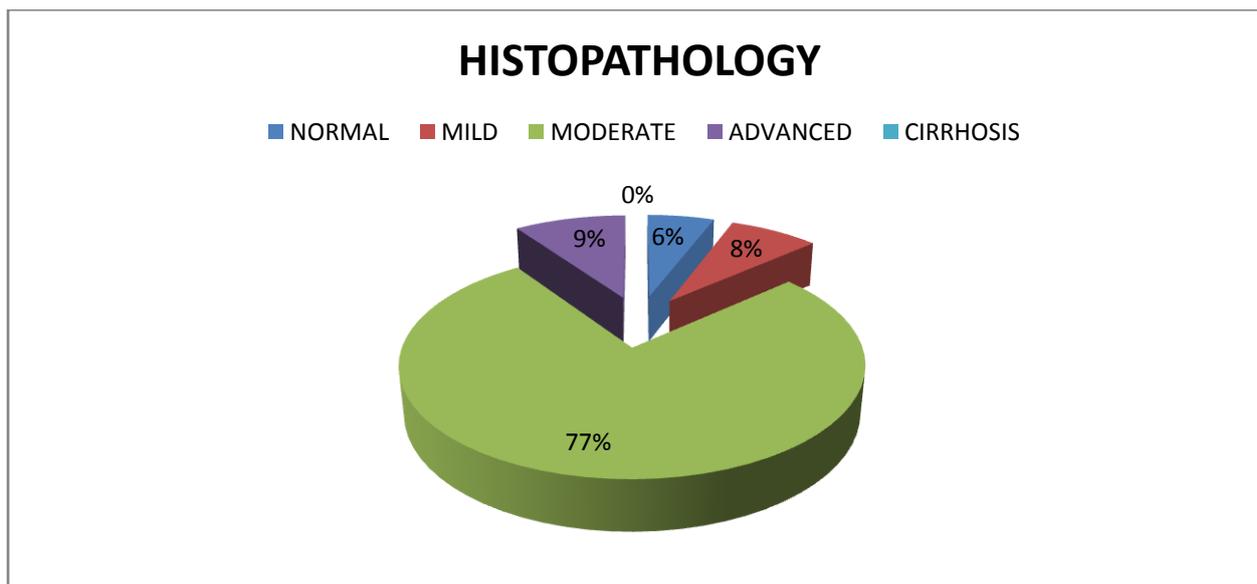
Fibroscan Results:

METAVIR SCORE	F0 (NORMAL)	F0-F1 (MILD FIBROSIS)	F2-F3 (MODERATE FIBROSIS)	F3-F4 (SEVERE FIBROSIS)
Number(n=58)	2	2	48	6



Histopathological findings:

Histopathological grade	NORMAL	F1 (MILD)	F2 (MODERATE)	F3 (ADVANCED)	F4 (CIRRHOSIS)
Number of cases (n=58)	3	4	40	5	6



1. Severe Fibrosis(FIBROSCAN)& cirrhosis (HPE); Total 6 patients were having severe fibrosis & cirrhosis. The Cohen’s kappa was 0.84(K= 0.84), & % of agreement was 96.6, showing almost perfect agreement between the Fibroscan results & Histopathology finding. Sensitivity (83.33%), specificity(98.08%), accuracy(96.5%),positive predictive value (83.33%),negative predictive value (98.08%).

		HPE- CIRRHOSIS (F4)	
		YES	NO
FIBROSCAN- SEVERE FIBROSIS (F3-F4)	YES	5	1
	NO	1	51
TOTAL (n=58)		6	52

2. Moderate Fibrosis (FIBROSCAN) & Moderate to Advanced (HPE); Total 45 patients were having moderate to advanced fibrosis on HPE & 48 patients having moderate fibrosis on Fibroscan. The Cohens kappa was 0.837(K=0.837), & percentage of agreement was 94.82%, showing almost perfect agreement between the Fibroscan results & Histopathological findings. Sensitivity (100%), Specificity (76.92%), Accuracy(94.83%),Positive predictive value (93.75%), Negative predictive value (100%).

		HPE-MODERATE TO ADVANCED FIBROSIS(F2-F3)	
		YES	NO
FIBROSCAN- MODERATE- FIBROSIS(F2-F3)	YES	45	3
	NO	0	10
	TOTAL(n=58)	45	13

3. Mild Fibrosis (FIBROSCAN & HPE); Total 4 patients were having mild fibrosis on HPE & 2 patients having mild fibrosis on FIBROSCAN. The Cohens kappa was 0.65(K=0.65), & percentage of agreement was 96.55%, showing Substantial agreement between the Fibroscan results & Histopathological findings. Sensitivity (50%), Specificity (100%), Accuracy(96.55%),Positive predictive value (100%), Negative predictive value (96.43%).

		HPE- MILD FIBROSIS(F1)	
		YES	NO
FIBROSCAN- MILD FIBROSIS (F0-F1)	YES	2	0
	NO	2	54
TOTAL(n=58)		4	54

4. Normal (FIBROSCAN & HPE); Total 3 patients were normal on HPE & 2 patients were normal on FIBROSCAN . The cohens kappa was 0.79(K=0.79), && percentage of agreement was 98.27%, showing Substantial agreement between the Fibroscan results & Histopathological findings.

Sensitivity (50%), Specificity (100%), Accuracy(96.55%),Positive predictive value (100%), Negative predictive value (96.43%).

		HPE- NORMAL	
		YES	NO
FIBROSCAN- NORMAL(F0)	YES	2	0
	NO	1	55
TOTAL(n=58)		3	55

IV. Discussion :

Liver fibrosis is primarily caused by hepatitis B, hepatitis C, alcoholic & non alcoholic steatohepatitis (NASH). Timely and accurate diagnosis of liver cirrhosis is essential for prevention and treatment of chronic liver disease . Liver biopsy is considered as the gold standard for diagnosing liver fibrosis. But liver biopsy is an invasive procedure and can not reflect the condition of whole liver., due to small sample size in liver biopsy. Fibroscan for assessing the liver stiffness is more helpful being non-invasive, easily available, more convenient, less inter observer variations and assessment of a large area of liver. And fibroscan can be repeated several times for long term follow up of chronic liver disease patients, without any complications or inconvenience to patient.

V. Conclusion:

In our study total 58 patients were studied which were admitted with chronic liver disease in department of medicine and gastroenterology , medical college Kolkata. Results of FIBROSCAN were compared with the histopathology using IDoStatics Cohen’s kappa calculator and med calculator . The results of FIBROSCAN for moderate and severe fibrosis were having perfect agreement& mild fibrosis to normal having substantial agreement with histiopatholgical finding’s, showing the FIBROSCAN as a perfect tool for assessing the liver fibrosis.

FUTURE DIRECTIONS : Two clinically available and FDA approved imaging techniques for assessing liver stiffness are Ultrasound (FIBROSCAN) and Magnetic Resonance Elastography (MRE), which are compared . The strengths & limitations of these two techniques may yield better screening and diagnostic model when used in combination than used separately.

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	AGE(YRS)	DIAGNOSIS	MED(kPa)	MED(m/s)	IQR(kPa)	IQR(m/s)	IQR/MED		FIBROSCA	HISTO
1	53	HepB	18.31	2.47	1.08	0.08	5.90%	3.00%	severe	cirrhosis
2	60	HepB	7.74	1.61	0.74	0.08%	9.50%	4.80%	moderate	moderate
3	59	HepB	10.08	1.83	1.49	0.14	14.70%	7.50%	moderate	moderate
4	54	HepB	11.25	1.93	1.36	0.11	12.10%	5.90%	moderate	cirrhosis
5	51	HepB	9.14	1.75	1.78	0.17	19%	9.90%	moderate	moderate
6	39	HepB	5.79	1.39	1.28	0.15	22%	10.70%	moderate	moderate
7	54	NALD	9.23	1.75	0.76	0.07	8.20%	4.10%	moderate	moderate
8	40	HepB	7.21	1.55	0.62	0.07	8.50%	4.30%	moderate	moderate
9	33	HepB	3.07	1.01	0.37	0.06	12.20%	6.10%	normal	normal
10	44	HepB	5.96	1.41	0.99	0.11	16.50%	8.10%	moderate	moderate
11	39	HepB	5.86	1.4	0.77	0.09	13.10%	6.50%	moderate	moderate
12	32	HepB	5.46	1.35	0.55	0.07	10%	5.10%	mild	mild
13	48	HepB	6.47	1.47	0.4	0.05	6.20%	3.10%	moderate	moderate
14	33	HepB	9.32	1.76	0.8	0.08	8.60%	4.30%	moderate	advanced
15	31	HepB	4.3	1.2	0.74	0.1	17.30%	8.70%	normal	normal
16	46	HepB	6.91	1.52	0.37	0.04	5.30%	2.70%	moderate	moderate
17	49	HepB	7.77	1.61	0.92	0.1	11.90%	5.90%	moderate	moderate
18	32	HepB	8.92	1.72	0.38	0.04	4.30%	2.10%	moderate	moderate
19	40	HepB	6.98	1.52	0.17	0.02	2.50%	1.20%	moderate	moderate
20	51	HepB	8.57	1.69	1.56	0.15	18.20%	9.20%	moderate	moderate
21	35	HepB	6.3	1.45	1.22	0.14	19.30%	9.50%	moderate	moderate
22	39	HepB	6.8	1.51	0.56	0.06	8.20%	4.20%	moderate	moderate
23	41	HepB	6.5	1.47	1.12	0.13	17.20%	8.70%	moderate	moderate
24	30	HepB	6.26	1.44	0.31	0.04	5.00%	2.50%	moderate	moderate
25	51	HepB	5.95	1.41	1.37	0.16	23.10%	11.30%	moderate	moderate
26	33	HepB	6.7	1.49	0.37	0.04	5.50%	2.70%	moderate	moderate
27	31	HepB	6.79	1.5	79	0.09	11.60%	5.80%	moderate	moderate
28	40	HepB	6.08	1.42	1.23	0.14	20.30%	9.80%	moderate	moderate
29	42	HepB	14.26	2.18	1.14	0.09	8%	4%	severe	cirrhosis
30	49	HepB	7.26	1.56	1.72	0.18	23.70%	11.70%	moderate	moderate
31	30	HepB	6.5	1.47	0.76	0.09	11.70%	5.90%	moderate	mild
32	55	HepB	5.16	1.31	0.76	0.1	14.70%	7.50%	mild	mild
33	36	HepC	6.58	1.48	0.83	0.08	12.70%	5.20%	moderate	moderate
34	31	HepC	11.35	1.94	0.74	0.06	6.60%	3.30%	moderate	advanced
35	35	HepC	7.45	1.59	0.37	0.04	4.90%	2.40%	moderate	moderate
36	46	HepC	13.83	2.15	1.1	0.08	7.90%	4%	severe	cirrhosis
37	41	HepC	7.84	1.62	1.58	0.17	20.20%	10.40%	moderate	moderate
38	54	HepC	5.94	1.41	0.88	0.11	14.80%	7.50%	moderate	mild
39	39	HepC	6.6	1.48	0.84	0.1	12.70%	6.40%	moderate	moderate
40	40	HepC	12.97	2.08	2.41	0.19	18.50%	9.40%	severe	cirrhosis
41	40	NALD	11.53	1.96	0.67	0.06	5.80%	3.00%	moderate	moderate
42	31	HepB	7.01	1.53	1.45	0.17	20.60%	10.90%	moderate	moderate
43	53	NALD	5.89	1.4	0.35	0.04	5.90%	3.00%	moderate	moderate
44	32	HepB	10.6	1.88	0.86	0.08	8.20%	4.10%	moderate	advanced
45	39	NALD	7.03	1.53	1.51	0.16	21.40%	10.60%	moderate	moderate
46	41	HepB	6.75	1.5	0.71	0.08	10.50%	5.20%	moderate	moderate
47	43	HepB	22.35	2.73	4.47	0.28	20.00%	10.40%	severe	cirrhosis
48	50	HepB	6.18	1.44	1.22	0.14	19.70%	9.60%	moderate	moderate
49	58	NALD	7.05	1.53	1.11	0.12	15.80%	8.00%	moderate	moderate
50	46	HepB	11.02	1.92	0.58	0.05	5.20%	2.60%	moderate	advanced
51	41	HepB	7.34	1.56	0.42	0.04	5.70%	2.90%	moderate	moderate
52	39	NALD	6.45	1.47	0.74	0.08	11.50%	5.80%	moderate	moderate
53	34	HepC	8.53	1.69	0.84	0.08	9.80%	4.80%	moderate	moderate
54	31	HepB	10.46	1.88	1.4	0.13	13.40%	6.70%	moderate	moderate
55	57	HepB	10.6	1.88	0.86	0.08	8.20%	4.10%	moderate	moderate
56	44	HepB	12.4	1.98	1	0.09	5.90%	3.00%	severe	moderate
57	49	HepB	10.02	1.83	1.42	0.13	14.20%	6.90%	moderate	moderate
58	38	HepB	10.49	1.87	0.6	0.05	5.70%	2.90%	moderate	advanced