Original Article

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To Predict the Occurrence of Esophageal Varices in Chronic Liver Disease Patients Using Transient Elastography (Fibroscan)

Deepankar Shivam[1], **Jigar M. Haria**[2], **V.K. Singh**[3], **Amit Kumar Mishra**[4], **Alok Singhal**[2], **Prashant Dubey**[4], **Hare Krishna**[4]

[1]Post Graduate Student, Department of Medicine, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh, India, [2]Professor, Department of Medicine, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh, India, [3]Professor & Head, Department of Medicine, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh, India, [4]Associate Professor, Department of Medicine, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh, India.

Abstract

Background: Chronic liver disease (CLD) is a cause of significant morbidity all over the world including India. Progression of CLD to cirrhosis leads to multiple complications including development of esophageal varices (EV) with its risk of bleeding & consequent morbidity & mortality. Hepatic biopsy with its inherent limitations is still the gold-standard tool for diagnosis of cirrhosis while Upper gastrointestinal Endoscopy (UGIE) with its inherent limitations is still the gold-standard tool for diagnosis of EV in these patients. Transient elastography (TE-Fibroscan) is a recently developed tool for estimating hepatic fibrosis by liver stiffness measurements (LSM) to predict cirrhosis as well as EV in cirrhotic patients. **Subjects and Methods:** One hundred patients of CLD were enrolled and evaluated by Fibroscan for LSM and by UGIE for EV & their grades following approval from Institutional Ethics Committee and after obtaining the informed consent. Various statistical methods and tools were then used to find out correlation of LSM with grade of EV and bleeder vs non-bleeder EV. **Results:** Majority of the patients were males with 41-50years being the dominant age-group. HCV followed by NAFLD were the commonest identifiable etiologies in our study group. Patients with small varices outnumbered those with large varices (52 vs 39). The mean LSM value increased significantly from no Varices (14.60 ± 0.88) to Small esophageal varices (15.51 ± 2.76) to Large esophageal varices (23.80±3.17) with positive correlation with variceal grade. Mean LSM value for identification of varices was 15.51±2.76kPa while it was 23.80±3.17 kPa for large varices. The bleeders had significantly higher LSM value compared to the non-bleeders (34.93±10.45kPa vs 18.46±5.59kPa). Significantly positive correlation was found between mean LSM; Total, Direct & Indirect Bilirubin; Alkaline Phosphatase and serum Globulin while negative correlation was noted with serum Albumin. **Conclusion:** The noninvasive nature of TE (Fibroscan) makes it an attractive tool for screening of CLD patients needing UGIE not only for diagnosis of EV but those with large varices needing management. Thus, TE might play a crucial role in not only diagnosis but also in management of EV varices in patients with CLD obviating unnecessary UGIE.

Keywords: Esophageal varices, Chronic Liver Disease, Transient Elastography, Fibroscan.

Corresponding Author: Deepankar Shivam, Post Graduate Student, Department of Medicine, Teerthanker Mahaveer Medical College & Research Centre, Moradabad, Uttar Pradesh, India.
E-mail: deepankarshivam@gmail.com

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Introduction

Chronic liver diseases (CLD) represent a crucial world public health problem with a prevalence of 4.5% to 9% around the world.[1] As per the data available it has been discovered that most of the rise in deaths due to CLD is from low and low middle income countries of Asia and Africa.[2]

Portal hypertension (pHTN) is the highest recurring and deadly concern of CLD. As a continuation, it furthers into gastro esophageal varices, hypersplenism, hepato-renal, hepato-pulmonary syndrome, ascites & hepatic encephalopathy. Often the aftermath of fibrosis advancement is pHTN which in turn leads to spread of esophageal and bloated gastric varices responsible for variceal bleeding and various other lethal complexities like subacute bacterial peritonitis, sepsis and portosystemic encephalopathy.[3]

The emergence of esophageal varices and poorer prognosis are related to clinically relevant pHTN (CSPH), defined as HVPG >10mmHg. With each instance of bleeding a minimum of 20%-30% is the mortality rate.[4]

The chronic liver insult gives way to development of liver fibrosis. The size and stage of the liver fibrosis are the deciding

factors for the diagnosis and treatment.[5,6]

The most important juncture of CLD is the commencement of Extracellular matrix protein desposition. There will be reduced liver function and hemodynamics, an increase in the propensity of the hepatocarcinogenesis and complexities due to pHTN, due to liver fibrosis.[7]

Liver biopsy is still considered to be the gold standard tool to analyze and quantify the level of liver fibrosis, but it is limited by not only improper sampling but biopsy may ignite faster spread as well as the interpretations may have an observer bias.[8–11]

To evaluate and identify the level of firmness in the liver, Fibroscan (Transient Elstography) has come up as a new technique, which can non-intrusively help in identification and evaluation of esophageal varices in cirrhosis.[12]

Similar technique is used to analyze and identify 'soft tissue' solid malignancies such as in prostate & breast cancer.[13]

Multiple studies have proven that TE is reliable alternative to liver biopsy for identifying and evaluating the level of LSM in patients with long standing condition.[14–16]

A very important step in ensuring prevention of variceal bleeding in sufferers with risk of variceal hemorrhage due to large EV, is by performing UGIE.[17,18] Increased economic burden and increased rejection of UGIE by suffering patients due to improper sedation are the key limitations.

To identify presence of pHTN in patient, TE may be useful. The Measurement of Liver stiffness may also help in predicting the presence of large EV in case liver cirrhosis, hence this can help in identification of patients needing endoscopic screening.[19–21]

The grade correlation exists in the association of esophageal varices to severity of disease with nearly 40% patients with liver cirrhosis have varix at the time when they are diagnosed.[4]

Aim and Objectives

AIM:

- To predict the occurrence of Esophageal Varices in Chronic Liver Disease patient using Transient elastography [Fibroscan].

Objectives:

- To obtain LSM value via Transient Elastography in all patient of CLD.
- To grade oesophageal varices determined using endoscopy in these patients.
- To compare the LSM values between bleeding v/s non-bleeding esophageal varices.
- To statistically predict the occurrence of bleeding esophageal varices using LSM in CLD with/without history of bleeding episode.

Subjects and Methods

This cross-sectional study was conducted in 100 patients of chronic liver disease over a period of 12months in the Department of Internal Medicine, Teerthanker Mahaveer Medical College and Research Center, Moradabad, Uttar Pradesh, who gave informed written consent following approval from Institutional Ethics committee with the following inclusion and exclusion criteria:

Inclusion Criteria

- All the patients with age more than 18 years with diagnosis of CLD.

Exclusion Criteria

- All severely ill patient who cannot undergo UGIE.

Each patient's medical history, personal history, family history and treatment if any, was recorded followed by their blood investigations. Patients were also evaluated with CXR PA view, USG W/A, Upper GI Endoscopy, Transient Elastography.

LSM values were recorded in all CLD patients using Transient Elastography. The grades of esophageal varices determined using upper GI endoscopy.

LSM values were correlated with the grade of oesophageal varices. LSM values were also compared between bleeding and non-bleeding esophageal varices.

Appropriate statistical tests were used to analyze the results. The p-value less than 0.05 was considered significant.

Results

Table 1: Mean Age Of Study Population

	Mean	Std. Deviation	Varian	Minim	Maxim	Range
Age (years)	45.22	11.79	139.08	16.00	80.00	64.00

Study population mean came to be 45.22±11.79 years. [Table 1]

Study population consisted of 65 (65.0%) males and 35 (35.0%) females. [Table 2]

Table 2: Gender Distribution

Gender	Frequency	Percent
Male	65	65.0%
Female	35	35.0%
Total	100	100.0%

Table 3: Aetiology of Chronic Liver Disease

Aetiology of CLD	Frequency	Percent
Alcohol	8	8.0%
HBsAg	18	18.0%
HCV	47	47.0%
HCV and HbsAg	4	4.0%
NAFLD	23	23.0%
Total	100	100.0%

The Aetiology CLD was found Alcohol among 8 (8.0%), HBsAg among 18 (18.0%), HCV among 47 (47.0%), HCV and HbsAg among 4 (4.0%) and NAFLD among 23 (23.0%) subjects. [Table 3]

No varices were found among 9 (9%), Small esophageal varices were found among 35 (35.0%), Small esophageal varices with mild PHG among 17 (17.0%), Large esophageal varices with Mild PHG among 22 (22.0%), Large esophageal varices with Moderate PHG among 6 (6.0%) and Large esophageal varices with severe PHG among 11 (11.0%) patients.

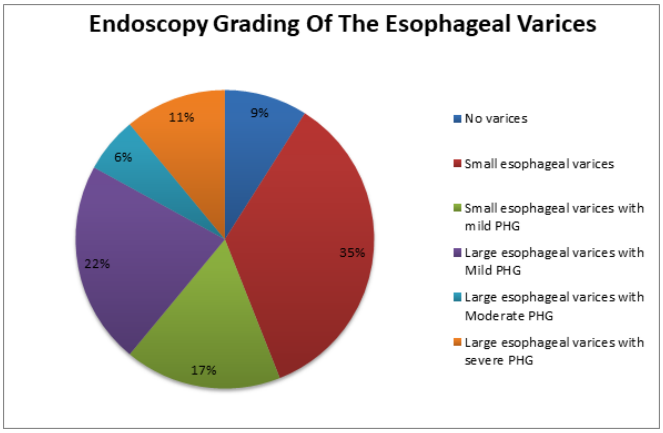

Chart 1: **Aetiology of Chronic Liver Disease**

The mean Fibroscan value increased significantly from No Varices to Small esophageal varices to Small esophageal varices with mild PHG to Large esophageal varices, Mild PHG to Large esophageal varices with Moderate PHG to Large esophageal varices with severe PHG. [Table 4]

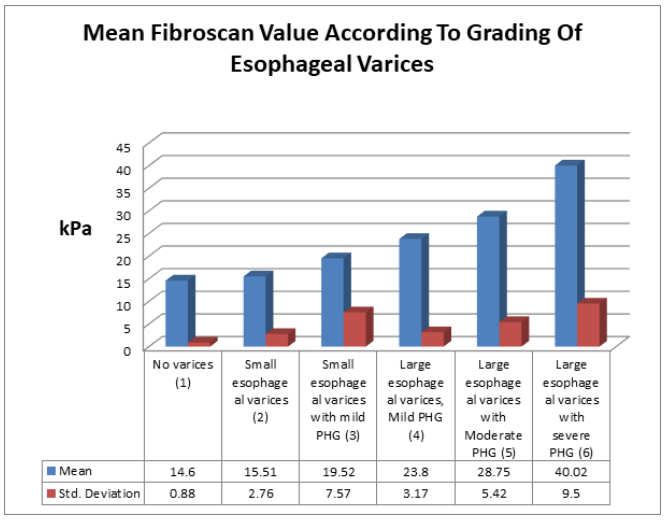

Chart 2: **Mean Fibroscan Value According To Grading of Esophageal Varices**

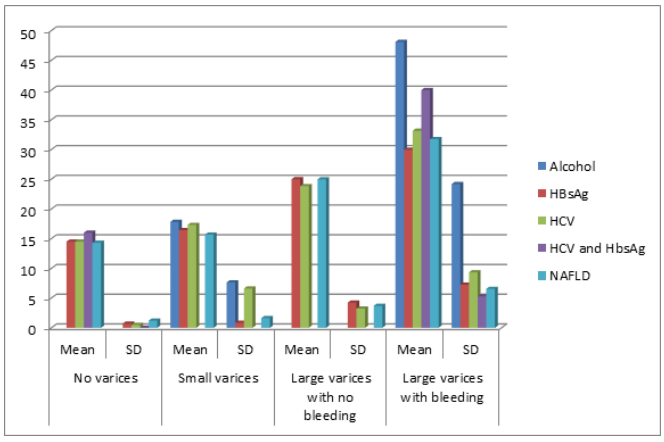

Chart 3: **Mean FibroscanValue In Accordance With The Causes of CLD**

The bleeders had significantly higher Fibroscan value compared to the non-bleeders. [Table 6]

Discussion

UGIE is considered best for analyzing the varices. It should done in the patient of cirrhosis at the time of presentation.[22]

As UGIE is not acceptable to many patients hence, there is a need for non-invasive technique like TE.[23,24] Liver stiffness measurement using Fibroscan is consistent and non-dependent of the operative user.[14] Specimen volume covered is 100 times than the biopsy and thus represent larger part hepatic parenchyma.[25]

Table 4: Mean Fibroscan Value According To Grading of Esophageal Varices

	Fibroscan			
Grading of Varices	**Mean**	**SD**	**p-value**	Post-hoc comparisons
No Varices (1)	14.60	0.88	< 0.001*	6 > 5 > 4 > 3 >2 > 1
Small esophageal varices 2)	15.51	2.76		
Small esophageal varices with mild PHG(3)	19.52	7.57		
Large esophageal varices, Mild PHG (4)	23.80	3.17		
Large esophageal varices with Moderate PHG (5)	28.75	5.42		
Large esophageal varices wi th severe PHG (6)	40.02	9.50		

Table 5: Mean FibroscanValue In Accordance With The Causes of CLD

Types of CLD	**No varices**		**Small varices**		**Large varices with no bleeding**		**Large varices with bleeding**	
n=100	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Alcohol (n=8)			17.82	7.64			48.1	24.18
HBsAg (n=18)	14.5	0.71	16.43	0.85	25	4.24	29.95	7.26
HCV (n=47)	14.5	0.5	17.31	6.6	23.84	3.23	33.16	9.33
HCV and HbsAg (n=4)	16						40	5.29
NAFLD (n=23)	14.3	1.21	15.68	1.64	24.98	3.7	31.75	6.55

Table 6: Mean Fibroscan Value In Bleeder & Non-Bleeder

	Fibroscan						
Bleeder	**Mean**	**S.D**	**Mean Difference**	**t-test value**	**p-value**		
No	18.46	5.59	-16.48	-16.044	0.001*	-30.23	-21.68
Yes	34.93	10.45					

Mean population age came to be “45.22±11.79 years” in our study, consisting mainly of “41-50 years (35.0%)”. This was in accordance with the study by Eh Lehleh et al.[26] the mean age of cases with esophageal varices was “49.92±6.45 years”, Foucher et al.[27]mean for age came to be “52.00±13.00 years” and Sarkar et al.[48]it was seen that cirrhosis was predominantly present in fifth decade (27.7%).

In our study, the study population comprised of 65.0% males and 35.0% females which was like the study done by Eh Lehleh et al.[26] 72.0% were males and 28.0% were females, Foucher et al.[27] 57% were males, Saad et al.[28] majority were males.

In current study, out of 100 cases the Aetiology for CLD was found be HCV among 47.0%, NAFLD among 23.0%, HBsAg among 18.0% Alcohol among 8.0%, HCV and HbsAg among 4.0% subjects.

Foucher et al.[29] had C-related (55.9%), B related 43(6%), liquor related (12.51%), C related & liquor related (3.65%), C related & HIV (3.37%), steatohepatitis not related to liquor (3.65%), Inherited disorder of iron overload (2.39%), cholestatic related (1.82%), and remaining other (10.54%).

Bisher sawaf et al.[30] found that 58.01% had NAFLD and B related 14.41%, C related 11.12%, liquor related 7.42%, drug causes 3.21%, cholestatic related 3.12% and immune related 2.01%.

Majority of the subjects in the present study had Small esophageal varices (35.0%) followed by Large esophageal

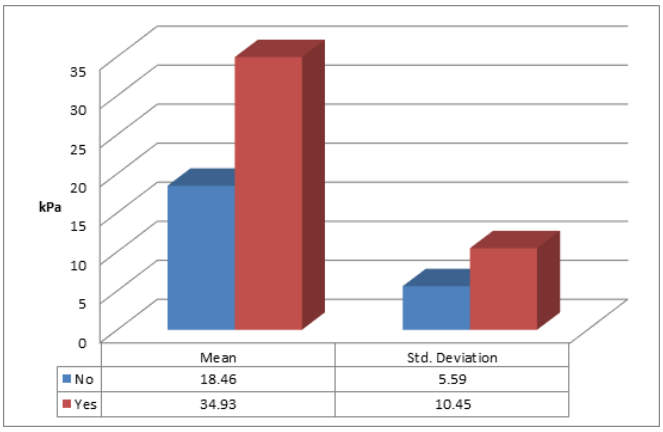

Chart 4: **MeanFibroscan value in Bleeder & Non-Bleeder**

varices with Mild PHG (22.0%), Small esophageal varices with mild PHG (17.0%), Large esophageal varices with severe PHG (11.0%), No varices (9%) and Large esophageal varices with Moderate PHG (6.0%). The mean Fibroscan value increased with the severity of the esophageal varices.

El Lehleh et al.[26] had 25 patient with no proof of esophageal varices (EV) by UGIE, and 50 patients had esophageal varices including 38 patients with small & 12 with large EV.

The "sensitivity and specificity of TE came to be 90%" for patients with cirrhosis.[31] The cut-off for cases with hepatitis C infection (HCV) disease and cirrhosis ranges from "11 to 17 kPa". The "sensitivity and specificity are around 70% to 80% for F2 to F4" fibrosis.[16]

In our study we found the positive correlation of increasing fibroscan value with the endoscopic variceal grading in already diagnosed (CLD) patient in accordance with severity. Mean LSM value for identification of varices among 35 cases out of 100 patients came to be 15.51 ± 2.76 kPa, p-value < 0.001.

Vizzutti et al.[21] found that LSM correlated with EV, decided "17.62kPa" as the cut-off estimation for foreseeing EV, "sensitivity 90% & specificity 43%". Likewise, Bureau et al.[32] found that LSM with a "cut off of 21 kPa" can anticipate EV in patients with CLD, with "89.9% sensitivity and 93.2% specificity". An study by Horia et al.[33] anticipated presence of EV at a "cut off of 19 kPa" with "sensitivity of 84%".

Pár et al.[34] presumed that noninvasive LSM by fibroscan permits to foresee the Varix & identify the screening populace, as they discovered high estimation "sensitivity of 85% and specificity of 87% at a cut off of 19.2 kPa" liver firmness for the presence of EV. Adriana et al.[35] estimate "cut off >15 kPa has sensitivity 95.51% & specificity 100%" in anticipating EV. Horia et al.[33] detailed that presence of EV can be anticipated at a "cut off estimation of 21.1 kPa".

El Lehleh et al.[26] found the best "cut off value 22.7 kPa" for the presence of varices. Kazemi et al.[36] found that the optimal "cut-off 13.91kPa with 95% sensitivity & 43% specificity" for forseeing the presence of varices.

Hu Z et al.[37] detailed that liver firmness of more than "25.5 kPa" could be used as a cut off for foreseeing EV with "84.1% sensitivity, 72.5% specificity, PPV 71.7%, NPV 90.8%, and AUROC 85.5%". Sharma et al.[38] stated a "cut-off value of 27.3 kPa with 91% sensitivity and 72% specificity" for the detection of varices. Sporea et al.[39] found a "cut-off value more than 29.5 kPa with 77.5% sensitivity, 86.9% specificity, and 78.9%" for prediction of significant EV.

Yasmin et al.[40] found that fibroscan was a good marker for the prediction of small EV "cut off>29.01kPa with 95% sensitivity & 67% specificity".

Adriana et al.[35] stated "cut off >28.80kPa with sensitivity 87.2% & specificity 82.76%" for presence of large varices. Yasmin et al.[40] detailed that fibroscan was an indicator of large EV "cut off >38kPa with 100% sensitivity & 77.3% specificity". Kazemi et al.[36] revealed that the ideal "cut off point 19kPa",in identifying large estimated varix with "sensitivity 91% & specificity 60%".

Saad et al.[28] indicated that liver firmness estimation was greater in large varix as compared to small , "cut off >38.2kPa" for large varices with "sensitivity of 100% & specificity of 77.3%".

A recent Cochrane survey analyzed transient elastography in 834 alcoholic liver disease patients from 5 review studies and 9 planned studies.[20] The author's said that transient elastography can be utilized when to rule out cirrhosis and might be useful when to rule out severe fibrosis, albeit a liver biopsy can be gotten if there is uncertainty in staging.[41]

The bleeders had significantly higher Fibroscan value compared to the non-bleeders respectively to be 34.93 ± 10.45 kPa, p-value <0.001 for the bleeder and 18.46 ± 5.59 kPa, p-value <0.001 for the non-bleeder.

Sporea et al,[39] found that values in bleeder & non-bleeder: "51.91 ± 1.57 kPa V/S 35.21 ± 0.92kPa, p< 0.0001". Foucher et al.[27] found "cut off>62.71kPa" for esophageal bleed to occur. As per Lebrec et al.[42] greater size is directly proportional to increase bleeding chances.

In our study, the mean Fibroscan value increased significantly from Normal (14.60 ± 0.88) to Small esophageal varices (15.51 ± 2.76) to Small esophageal varices with mild PHG (19.52 ± 7.57) to Large esophageal varices with Mild PHG (23.80±3.17) to Large esophageal varices with Moderate PHG (28.75 ± 5.42) to Large esophageal varices with severe PHG (40.02 ± 9.50).

Conclusions

1. Males outnumbered female with M:F ratio of 1 9:1
2. The mean age was 45 22±11 79 years with 41-50 years age-group predominating (35 0%
3. HCV related cirrhosis was the predominant group with 47 0% followed by NAFLD 23 0% subjects
4. Small esophageal varices were found in higher number of subjects than large varies on UGIE being 52 vs 39.
5. The mean Fibroscan value increased significantly from No Varices (14.60 ± 0.88) to Small esophageal varices(15.51 ± 2.76) to Large esophageal varices (23.80±3.17) with positive correlation between fibroscan value and endoscopic variceal grading.
6. Mean LSM value for identification of varices was 15 51±2 76kPa
7. Mean LSM value for detecting large esophageal varices was 23 80±3 17 kPa
8. The bleeders had significantly higher Fibroscan value compared to the non-bleeders being 34.93±10.45kPa and 18.46±5.59kPa respectively.
9. Significantly positive correlation was found between mean LSM and Total, Direct & Indirect Bilirubin as well as with Alkaline Phosphatase.
10. Positive correlation of LSM values was noted with Globulin while negative correlation was noted with Albumin.

Limitations of Study

- Due to time bound nature, the number of cases included in the study were limited hence we were unable to show the rate of progression of fibrosis in the patients of different etiologies of CLD.
- Since the study population was selected from only one hospital and variceal grading was done by only one gastroenterologist, possibility of inter-observer variability could not be evaluated.

Summary

As LSM on Fibroscan significantly correlates with increasing esophageal variceal grade, it can be used to non-invasively evaluate patients with CLD helping in the prognostication as well as better management & treatment in patients with cirrhosis.

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