

# Evaluation of Non-Alcoholic Fatty Liver Disease Severity Using FIB-4 Score and Transient Elastography in Type-2 Diabetes Patients

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## Abstract

**Background:** Nonalcoholic fatty liver disease (NAFLD) is the most prevalent chronic liver disease. Fibrosis-4 (FIB-4) score is a screening tool for liver fibrosis detection and Transient elastography (TE) is recommended for liver stiffness measurement (LSM) in primary care settings for patients with metabolic risk factors and FIB-4 levels above 1.3. The present study was conducted to evaluate non-alcoholic fatty liver disease severity using FIB-4 score and transient elastography in type-2 diabetes patients. **Material and Methods:** Present research was done on 150 cases having Type-2 diabetes and NAFLD. NAFLD was diagnosed based on history, blood investigations and USG whole abdomen. 100 cases were segregated as Low risk [FIB-4 <1.3] whereas 50 as High risk [FIB  $\geq$  1.3; TE  $\geq$  8 kPa] cases. Data collected and recorded on MS excel. Data was analysed using SPSS version 20.0 software. **Results:** Lipid profile was comparable ( $p > 0.05$ ) in both high and Low risk cases. In Low risk, more cases showed good HbA1c and Grade 1 fatty liver than High risk, depicting a considerable difference ( $p < 0.05$ ). Average elastography values and Mean FIB 4 score were considerably ( $p < 0.05$ ) higher in High risk than Low risk cases. **Conclusion:** Use of different non-invasive fibrosis scores among patients with type 2 diabetes identifies different proportions of patients with advanced fibrosis. FIB-4 cut-offs results in a decrease in gray-zone results, making referrals to hepatologists more sustainable for the healthcare system.

**Keywords:** Nonalcoholic fatty liver disease; Diabetes; FIB-4 score; Lipid profile.

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## INTRODUCTION

The most prevalent chronic liver disease in the world is nonalcoholic fatty liver disease (NAFLD), which was recently renamed metabolic dysfunction-associated fatty liver disease (MAFLD) or metabolic dysfunction-associated steatotic liver disease (MASLD).<sup>[1]</sup> As characteristics of the metabolic syndrome (MetS), obesity, type 2 diabetes mellitus (T2DM), arterial hypertension, and dyslipidemia are comorbidities linked to non-alcoholic fatty liver disease (NAFLD).<sup>[2]</sup> Insulin resistance is one of the overlapping pathophysiological characteristics between type 2 diabetes (T2D) and non-alcoholic fatty liver disease (NAFLD), and both diseases worsen each other's prognoses.<sup>[3,4]</sup> NAFLD raises the risk of micro- and macrovascular complications in patients who already have T2D, as well as the risk of developing T2D in those who are not affected.

Liver biopsy remains the gold standard for the diagnosis of NAFLD and fibrosis, but it is pricey and carries risk. However, a number of trustworthy noninvasive techniques for assessing liver fibrosis have decreased the need for liver biopsies and given general practitioners a straightforward way to assess liver fibrosis. These days, NFS and FIB-4 are the most studied fibrosis biomarkers.<sup>[2]</sup> The fibrosis-4 (FIB-4) score has been proposed as a screening tool for liver fibrosis detection.<sup>[5]</sup> Transient elastography (TE) is recommended for liver stiffness measurement (LSM) in

primary care settings for patients with metabolic risk factors and FIB-4 levels above.<sup>[1,3,6]</sup>

A well-validated, non-invasive, straightforward, safe, and effective method with high diagnostic and prognostic accuracy, transient elastography (TE) has completely changed the way liver fibrosis is evaluated. The interpretation of the TE values may differ to some degree dependant of the cause of liver illness. The best results are interpreted by someone with experience in managing chronic liver disease and in conjunction with other clinical and/or biochemical markers.<sup>[7]</sup>

It is debatable, though, whether the same screening procedure should be used in tertiary care settings. In this study, we sought to determine the prevalence of advanced fibrosis among NAFLD patients who were referred to tertiary care settings and to analyze the diagnostic performance of FIB-4 and TE for screening liver fibrosis in patients with and without type 2 diabetes. Although

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the management of T2DM patients places more emphasis on controlling blood sugar and microvascular and macrovascular complications, the management of the NAFLD spectrum of disease is less important, despite the knowledge of the morbidity and mortality caused by cirrhosis. Thus the present study was conducted to evaluate non-alcoholic fatty liver disease severity using FIB-4 score and transient elastography in type-2 diabetes patients.

## MATERIALS AND METHODS

The present research study was done in the Deptt. of General Medicine from 2024 to May 2025. The study was done on 150 cases of either gender, aged >18yrs having Type-2 diabetes and NAFLD, attending OPD /IPD of Deptt. of General Medicine TMU were included in the study. The study was conducted after getting clearance from Institutional Ethical Committee clearance (IEC no.....) and written informed consent was taken from all study subjects. Cases with history of alcohol intake more than 30gm/day in males and 20gm/day in females; having chronic/acute viral hepatitis; patients having drug induced hepatitis; patients who had undergone liver transplantation and those with terminal illness were excluded from the study.

A thorough case history was taken from all patients, following by Liver functions test [LFT], Hemogram [CBC], Viral markers, Random blood sugar [RBS], HBA1C, Ultrasound whole abdomen, Transient elastography [TE].

NAFLD was diagnosed based on history, blood investigations and USG whole abdomen. 100 cases (66.67%) out of 150 were segregated as Low risk [FIB-4 <1.3] cases whereas 33.33% (n=50) were High risk [FIB  $\geq$  1.3; TE  $\geq$  8 kPa] cases. Data collected and recorded on MS excel. Data was analysed using SPSS version 20.0 software (IBM Chicago Ltd.).

## RESULTS

34.7% cases were aged >60yrs, with mean age being 55.26 $\pm$ 13.01yrs, depicting male predominance (52.7%). 66.67% cases were Low risk [FIB-4 <1.3] whereas 33.33% were High risk [FIB  $\geq$  1.3; TE  $\geq$  8 kPa] cases. 30% cases in low risk group had DM of 10-15yrs long, whereas in high risk group, 42% cases had more prolonged duration of >15yrs; depicting a considerable difference ( $p < 0.05$ ). Total Cholesterol and LDL levels were more in High risk cases but comparable ( $p > 0.05$ ) to Low risk; whereas Triglyceride and HDL levels were less in High risk but comparable ( $p > 0.05$ ) to Low risk cases. [Table 1]

In Low risk, 35% patients showed good HbA1c than 14% in High risk, depicting a considerable difference ( $p < 0.05$ ) between both the groups with HbA1c. [Table 2] In Low risk, more patients showed Grade 1 fatty liver than 66% in High risk, depicting a considerable difference ( $p < 0.05$ ) between both the groups with fatty liver. (Table no. 3) Average elastography values and Mean FIB 4 score were considerably ( $p < 0.05$ ) higher in High risk than Low risk. [Table 4 & 5]

**Table 1: Mean Lipid profile in Low and High risk patients**

| Lipid profile     | Low risk [FIB-4 <1.3] |           | High risk [FIB $\geq$ 1.3; TE $\geq$ 8 kPa] |           | Statistical analysis |          |
|-------------------|-----------------------|-----------|---------------------------------------------|-----------|----------------------|----------|
|                   | Mean                  | SD        | Mean                                        | SD        | t-test               | p-value* |
| Total Cholesterol | 159.5600              | 54.97296  | 163.8600                                    | 60.21865  | 1.910                | 0.067    |
| Triglyceride      | 217.6000              | 176.99849 | 213.6600                                    | 171.28430 | 2.009                | 0.901    |
| HDL               | 40.9020               | 13.82947  | 40.1760                                     | 13.69641  | 1.001                | 0.990    |
| LDL               | 72.9540               | 27.51990  | 73.5680                                     | 29.46921  | 2.156                | 0.077    |

\*p-value>0.05 is insignificant

**Table 2: HBA1C % in Low and High risk patients**

| HBA1C %         | Low risk [FIB-4 <1.3] |                | High risk [FIB $\geq$ 1.3; TE $\geq$ 8 kPa] |                |
|-----------------|-----------------------|----------------|---------------------------------------------|----------------|
|                 | Frequency (n)         | Percentage (%) | Frequency (n)                               | Percentage (%) |
| Good[<7]        | 35                    | 35             | 7                                           | 14             |
| Inadequate[7-8] | 23                    | 23             | 11                                          | 22             |
| Poor[>8]        | 42                    | 42             | 32                                          | 64             |
| Total           | 100                   | 100            | 50                                          | 100            |
| Chi square      | 1.332                 |                |                                             |                |
| p-value         | 0.036*                |                |                                             |                |

\*p-value<0.05 is significant

**Table 3: USG assessment (Grade of fatty liver) in Low and High risk patients**

| Grade of fatty liver | Low risk [FIB-4 <1.3] |                | High risk [FIB $\geq$ 1.3; TE $\geq$ 8 kPa] |                |
|----------------------|-----------------------|----------------|---------------------------------------------|----------------|
|                      | Frequency (n)         | Percentage (%) | Frequency (n)                               | Percentage (%) |
| Grade 1              | 77                    | 77             | 33                                          | 66.0           |
| Grade 2              | 23                    | 23.0           | 16                                          | 32.0           |
| Grade 3              | 0                     | 0              | 1                                           | 2.0            |
| Total                | 100                   | 100            | 50                                          | 100.0          |
| Chi square           | 2.780                 |                |                                             |                |
| p-value              | 0.046*                |                |                                             |                |

\*p-value<0.05 is significant

**Table 4: Mean Elastography values in Low and High risk patients**

| Elastography values [kpa] | Low risk [FIB-4 <1.3] |         | High risk [FIB $\geq$ 1.3; TE $\geq$ 8 kPa] |          |
|---------------------------|-----------------------|---------|---------------------------------------------|----------|
|                           | Mean                  | SD      | Mean                                        | SD       |
|                           | 5.6719                | 2.78993 | 20.3288                                     | 17.09222 |
| t-test                    | 2.819                 |         |                                             |          |

|         |        |
|---------|--------|
| p-value | 0.001* |
|---------|--------|

\*p-value<0.05 is significant

**Table 5: Mean FIB 4 score in Low and High risk patients**

| FIB 4 score | Low risk [FIB-4 <1.3] |         | High risk [FIB ≥ 1.3; TE ≥8 kPa] |         |
|-------------|-----------------------|---------|----------------------------------|---------|
|             | Mean                  | SD      | Mean                             | SD      |
|             | 1.6489                | 1.20908 | 3.2838                           | 1.94583 |
| t-test      | 1.415                 |         |                                  |         |
| p-value     | 0.049*                |         |                                  |         |

\*p-value<0.05 is significant

## DISCUSSION

Transient elastography (TE) and the FIB-4 score are both used to evaluate the existence of liver fibrosis and the severity of non-alcoholic fatty liver disease (NAFLD) in patients with Type 2 diabetes.<sup>8</sup> Enhancing TE's accessibility to frontline general practitioners can help identify advanced fibrosis and NAFLD. For their patients who were considered to be at high risk of liver disease, general practitioners in this trial had direct access to TE.<sup>[9]</sup> In this primary care referral population, we assess the relationship between the occurrence of T2DM with liver fibrosis and steatosis by TE. Fibrosis and liver-related consequences are reliably predicted by TE scores. There are, however, few research on its application in populations at risk for NAFLD. This prospective research was carried to evaluate non-alcoholic fatty liver disease severity using FIB-4 score and transient elastography in type-2 diabetes patients.

In accordance with our study, Chung SM et al,<sup>[3]</sup> found that mean age was 47.0 and 48.9yrs in without and with DM cases, having insignificant variation in concern to age. They also depicted male predominance (66.7%). This indicates more degrees of fibrosis linked with older age group. Transient elastography or an enhanced liver fibrosis (ELF) score should be used to further evaluate patients with an uncertain (1.3–2.67) FIB-4 score, according to the guidelines. According to current guidelines, the most reliable method for detecting advanced liver disease and forecasting liver-related outcomes is vibration controlled transient elastography, which is used in FibroScan. Average elastography values were considerably higher in High risk [FIB ≥ 1.3; TE ≥8 kPa] cases (20.33 kPa) than Low risk [FIB-4 <1.3] cases (5.67 kPa). Thallapureddy K et al.<sup>10</sup> observed that in high risk cases, elastography value was more 11.2 kPa, than low risk cases 6.3 kPa.

A non-invasive method for evaluating hepatic fibrosis, a disorder in which the liver gets scarred, is the Fibrosis-4 (FIB-4) score. Age, platelet count, ALT (alanine aminotransferase) levels, and AST (aspartate aminotransferase) levels are used in its computation. The necessity for additional testing, such as a liver biopsy, may be determined by a higher FIB-4 score, which often denotes a higher risk of advanced liver fibrosis. Mean FIB 4 score were considerably higher in High risk cases (3.28) than Low risk cases (1.65). Thallapureddy K et al,<sup>[10]</sup> observed FIB-4 score was more (1.72) in high risk cases than low risk (0.88). Gabriel-Medina P et al,<sup>[8]</sup> observed FIB 4 score as 1.5.

It would not be feasible to routinely refer all patients to professional hepatologists due to the rising incidence of

NAFLD, and it is difficult for doctors to identify the tiny percentage of patients who have an advanced form of the disease.<sup>[11-13]</sup> Large populations cannot be served by liver biopsy, therefore easily accessible non-invasive fibrosis testing are a very alluring alternative.<sup>[14-15]</sup> According to the aforementioned recommendations, our study is the biggest to date in this regard to assess the proportion of type 2 diabetic patients who ought to be sent to hepatologists.

Our study group is representative of the population that regularly sees diabetic clinics in a real-world context since we decided to include all patients referred to our clinic in order to inform routine clinical practice. Therefore, we think that this demographic could benefit from our findings. We decided to employ the diagnostic flow-chart utilizing FIB-4 even though we discovered a wide range in the proportion of patients categorized as having low–intermediate or high risk of advanced fibrosis depending on the particular biomarkers used. The guidelines also state that one of the most validated scores in the literature is FIB-4.

Our study has various promising facts; inclusion of both the sexes, a high grade of data collection, and a study sample that is representative of overall type 2 diabetes community who visits secondary care diabetic clinics, makes study results more promising. Furthermore, instead of using indicators of subclinical organ damage that had already been reported in earlier research, we decided to assess hard cardiovascular clinical outcomes. Use of Elastography technique gives more validated results.

Besides strengths, we also encountered few limitations; our study was carried on a limited sample size, thus future studies are recommended to be carried on a larger sample. This research is dependent on the outcomes taken from a single centre, so the results could not be applied to whole Indian population. Our suggestion is to do more number of prospective research studies as well as clinical trials involving elaborated population of India, so as to generalise the study results. The fact that many individuals fall into a gray area where the diagnosis is still uncertain is one of the main drawbacks of non-invasive scores. We excluded individuals based on their reports or the available medical records; we did not rigorously evaluate the presence of additional etiologies of liver disease.

## CONCLUSION

Use of age-adjusted FIB-4 cut-offs results in a decrease in gray-zone results, making referrals to hepatologists more sustainable for the healthcare system, even though the use of different non-invasive fibrosis scores among patients with type 2 diabetes identifies different proportions of patients with advanced

fibrosis. Although it still requires validation in the diabetologic scenario, further integration with other approaches is likely to further reduce ambiguous findings. Fascinatingly, a distinct pattern of diabetic complications was consistently linked to non-invasive biomarkers. Thus we advice to conduct prospective research studies as well as clinical trials in future on an elaborated sample incorporating a larger Indian population, in a way to generalise the results of our research.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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