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A Prospective Cohort Study To Estimate The Amount Of Scarring Of Liver In Non-Alcoholic Fatty Liver Disease In Type 2 Diabetes Patients

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ABSTRACT

Background: NAFLD encompasses a variety of disorders, including non-alcoholic fatty liver, non-alcoholic steatohepatitis (NASH), fibrosis, and cirrhosis. The FIB-4 index is primarily used to detect liver fibrosis in alcoholic and infectious liver disease patients. This study will aid in identifying people at risk of developing liver fibrosis in non-alcoholic fatty liver disease patients using the FIB-4 score.

Material and methods: A prospective study was undertaken among 31 patients with Nonalcoholic fatty liver disease. All patients were treated to a full clinical examination, including laboratory tests. All cases were subjected to CBC, RFT, and LFT investigations. Fibroscan and LSM were conducted according to manufacturer instructions.

Results: In this study, the mean BMI was 28.0, AST was 137.5, ALT was 74.0, platelet count was 166548.4, and HbA1c was 8.3. Approximately 64.5% of the cases had F4 grade fibrosis. The correlation coefficient between HbA1c and FIB-4 score was -0.135, which was negative but not significant.

Conclusion: It is critical that diabetics be checked for, recognized, and referred for advanced fibrosis in a proactive way.

Keywords: *NAFLD, FIB-4 score, fibroscan, fibrosis, T2DM*

1. INTRODUCTION

The most common chronic liver disease in western world in Nonalcoholic fatty liver disease [NAFLD].[1] In absence of secondary causes like alcohol and drugs, macro vesicular steatosis of >5% of hepatocytes is defined as NAFLD. NAFLD includes spectrum of diseases like nonalcoholic fatty liver, non-alcoholic steatohepatitis (NASH), fibrosis and cirrhosis.[2]

Some of risk factors for NAFLD are central obesity, Type 2 diabetes mellitus, dyslipidemia, and metabolic syndrome.[3] Weight loss, dietary modification, and the treatment of underlying metabolic syndrome are some of management options of patients with NAFLD.[4]

In primary care settings Fibrosis-4 [FIB-4] index can be used as a potential biomarker for identifying liver fibrosis. FIB-4 index can be used alternative to liver biopsy.FIB-4 index can be calculated by using simple parameters like age, alanine aminotransferase, aspartate aminotransferase and platelet count.[5, 6]

The FIB-4 index is proposed originally to assess the hepatic fibrosis in human immuno deficiency virus [HIV] patients and hepatitis-c patients [HCV].[7]

Nonalcoholic fatty liver disease is an alarming problem in the world and its incidence is increasing day by day due to inappropriate dietary habits, lack of exercise and also due to increase in prevalence of diabetes and metabolic syndrome. If not identified and treated in time NAFLD can develop into steatohepatitis and can also lead to liver fibrosis if not intervened.[8]

Liver biopsy is confirmatory test for liver fibrosis but it is a invasive procedure and cannot be used for routine screening. More over the need of equipment and trained practitioner for the procedure to be done makes it difficult to be performed in primary care settings. FIB-4 index is a simple non-invasive test, which requires simple routine blood tests to calculate and identify people at risk of liver fibrosis.[9]

FIB-4 index is mainly used to identify liver fibrosis in alcoholic and infectious liver disease patients. This study will help to identify patients at risk of developing liver fibrosis by using FIB-4 score in non-alcoholic fatty liver disease patients.

2. MATERIAL AND METHODS

A prospective cohort study was undertaken in Department of General Medicine of R L Jalappa Hospital, Sri Devaraj Urs Medical College, Tamaka, Kolar for a period of three months. A calculated sample size of 31 constituted the study sample. Sample size was estimated by using correlation coefficient (r) of FIB-4 Values with LSM on the FibroScan as 0.507 (i.e. r = 0.507) from the study by Ding et al.[7] Using these values at 95% confidence level and 80% power and substituting in the below formula, sample size of 28 was obtained. Considering 10% Non-response rate a sample size of 28 + 2.8 = 31 subjects were included in the study. Patients with non-alcoholic fatty liver disease with diabetes mellitus were included in to the study. Patients with unknown liver diseases, excessive alcohol intake, positive hepatitis B antigen, positive hepatitis C antibody, hepato toxic medications and autoimmune liver diseases were excluded from the study.

All patients were subjected for thorough clinical examination including Laboratory investigations. All the cases were subjected for CBC, RFT and LFT investigations. Fibroscan and LSM was performed on the basis of manufacturer guidelines. The details thus obtained was entered in pre designed proforma and compiled and analysed.

3. RESULTS

Table 1. Distribution of the study group according to baseline characteristics

		Frequency	Percent
Age group	**41 – 50 years**	2	6.5
	51 – 60 years	9	29.0
	More than 60 years	20	64.5
Sex	**Male**	8	25.8
	Female	23	74.2
BMI	**18 – 23**	2	6.5
	23 – 27.4 (Overweight)	9	29.0
	More than 27.5 (Obesity)	20	64.5
	Total	31	100

This study had shown that, about 64.5% of the cases were aged more than 60 years and 74.2% were females. The BMI was more than 27.5 in 64.5% of the cases.

Table 2. Clinical parameters in the study group

	Minimum	Maximum	Mean	SD
BMI	22.0	32.0	28.0	2.8
AST	126.0	148.0	137.5	5.2
ALT	34.0	104.0	74.0	18.8

PLT	68000.0	309000.0	166548.4	56728.5
HbA_{1c}	6.3	11.0	8.3	1.2

Mean BMI was 28.0, AST levels were 137.5, ALT levels were 74.0, Platelet count was 166548.4 and HbA_{1c} level was 8.3 in this study.

Table 3. Grading of fibrosis

Fibrosis grade	Frequency	Percent
F2	2	6.5
F3	9	29.0
F4	20	64.5

About 64.5% of the cases had F4 grade of fibrosis, 29.0% had F3 grade of fibrosis and 6.5% of the cases had F2 grade fibrosis.

Table 5. Correlation between the HbA_{1c} levels and FIB - 4

Correlations

		HbA1c	FIB - 4
HbA1c	Pearson Correlation	1	-.135
	Sig. (2-tailed)		.470
	N	31	31
FIB - 4	Pearson Correlation	-.135	1
	Sig. (2-tailed)	.470	
	N	31	31

The correlation coefficient between the HbA_{1c} and FIB – 4 score was -0.135 which was negative and not significant.

4. DISCUCSSION

This study was undertaken in order to estimate the amount of scarring of liver in non-alcoholic fatty liver disease in type 2 diabetes mellitus cases. The prevalence of fibrosis was 93.5% in this study among NAFLD cases. Advanced fibrosis was strongly connected with advancing age, the length of diabetes, and worse glycaemic management, as shown by a greater HbA1c. The study's participants were diabetic individuals with varied diabetes durations and higher BMIs, which meant they had a higher metabolic burden than they would have in the community.

The frequency of advanced fibrosis ranged from 2.8% to 5.6%, according to a retrospective analysis of 1131 diabetes patients utilising Fibroscans. Between 5% and 35% of diabetics in European and Australian studies had elevated LSM; however, the cutoffs, or LSM values, used to identify fibrosis varied. [10, 11, 12, 13, 14]

In a study, 62 (22.3%) people had an LSM value of 11.5 or higher, indicating cirrhosis. Previous histological studies have shown that hyperglycemia is one of the most significant risk factors for cirrhosis in patients with NAFLD. Men with diabetes are also twice as likely to get hepatocellular cancer.[15]

5. CONCLUSION

This study reported a high prevalence of NAFLD in cases with advanced liver fibrosis in people with diabetes. Individuals with diabetes who are older, have had the disease for a longer period of time, have a high body mass index, and have uncontrolled diabetes may be more susceptible to advanced fibrosis and should be evaluated for liver disease. Diabetologists

frequently overlook screening for NAFLD and advanced fibrosis, therefore it is imperative that individuals with diabetes be screened for, identified, and referred for advanced fibrosis in a proactive manner.

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