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Study of prevalence of non- alcoholic fatty liver disease in type 2 diabetes and its correlation with liver function tests and fasting lipid profile

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***Abstract*---**Introduction: NAFLD is the third leading indication for liver transplantation. The prevalence of NAFLD has been documented to be 15%-30% in general population and 70%-75% in type 2 diabetes population. Indian population has a higher body fat content and abdominal adiposity: the more upper body fat content is associated with insulin resistance causing more NAFLD. There is evidence that Type 2 DM patients with NAFLD are at higher risk of developing cirrhosis compared to non-diabetic patients. The present study was conducted in a tertiary care hospital from south India to know the Prevalence of Non -Alcoholic Fatty Liver Disease in persons with Type 2 Diabetes Mellitus and to correlate the results of Liver Function Tests and fasting Lipid Profile with NAFLD. Materials and Methods: This is an observational study done in patients attending OPDs in department of General Medicine during 1st January 2018 to 30th June 2019 in Maharajah's Institute of Medical Sciences, Vizianagaram and Andhra Pradesh. Results: The prevalence of NAFLD, as assessed by ultrasound examination, was 67%, mean age of subjects in the NAFLD group was 53.06 ± 6.20 years. Prevalence in males was 45.2%. High BMI is associated with NAFLD (P< 0.001). There was no statistically significant difference in FBS, PPBS, HbA1C levels between the two groups. There is increased triglyceride levels, low HDL in the diabetic fatty liver group as compared to non-fatty liver

group. There was no significant difference in the mean LDL and Total cholesterolin the NAFLD group and the normal liver group. Mild to moderate levels elevation of levels of ALT, AST or both is a very common finding in NAFLD. Conclusion: The prevalence of NAFLD is high among diabetic patients. High BMI is associated NAFLD. Increased triglyceride levels and low HDL seen. In diabetic fatty liver. It is crucial to diagnose NAFLD at an early stage because it is potentially treatable.

***Keywords*---**NAFLD- Non -Alcoholic Fatty Liver Disease, LFT-Liver Function Tests, FLP-Fasting Lipid Profile, HbA1c - Glycosylated hemoglobin, BMI- Body Mass Index, TG- Triacylglycerols.

Introduction

The word NAFLD is used to describe a wide array of changes from simple steatosis to steatohepatitis, cirrhosis , in the absence of excessive alcohol intake.[1] Now it's considered as one of the most frequent in the industrialized world.[2] NAFLD is the third leading indication for liver transplantation.[3] The prevalence of NAFLD has been documented to be 15%-30% in general population and 70%-75% in type 2 diabetics.[4] There is evidence that Type 2 DM patients with NAFLD are at higher risk of developing cirrhosis compared to non-diabetic patients.[5] Indian population has a higher body fat content and abdominal adiposity, the more upper body fat content is mainly associated with insulin resistance and hence NAFLD.[6]

Ultrasonogram is the method of choice for screening patients for NAFLD. Liver biopsy is considered to be an ideal method to diagnose and staging NAFLD. But, it is a costly and invasive procedure with limitations.[7] A biopsy is typically indicated when liver tests shows elevated enzymes chronically (e.g., for six months) which are of unexplained etiology. It is crucial to diagnose NAFLD at an early stage because it is potentially treatable and hence can prevent patients from going into cirrhosis.[8]

Aims and Objectives

The present study aimed to study the Prevalence of Non -Alcoholic Fatty Liver Disease in persons with Type 2 Diabetes Mellitus and to correlate the results of Liver Function Tests and fasting Lipid Profile with Ultrasonographic evidence of fatty liver in Type 2 Diabetes Mellitus in a tertiary care hospital from south India

Materials and Methods

This is an observational study done in patients attending outpatient department in department of General Medicine, Maharajah's Institute of Medical Sciences, Vizianagaram, Andhra Pradesh.

Study Design: Observational study.

Study Setting: Maharajah's Institute of Medical Sciences, Vizianagaram, Andhra Pradesh.
Study Population: 100 patients who were diagnosed to have Type 2 Diabetes Mellitus belonging to both sexes and age more than 40 years attending the General Medicine Out-patient department during the period of 1st January 2018 to 30th June 2019.

Inclusion Criteria: Patients who were diagnosed to have Type 2 Diabetes Mellitus belonging to both sexes and age more than 40 years.

Exclusion criteria
Patients with a history of alcohol consumption for any duration, Persons with the previous history of jaundice, ascites, and signs of liver failure, who tested positive for Hepatitis B, Hepatitis C serology by Elisa, or by card test were excluded, Patients with a history of drug intake that can cause fatty liver, Patients with Nephropathy, Congestive Cardiac Failure (CCF) were excluded.

Study Duration: From 1st January 2018 to 30th June 2019.

Data Collection

After getting approval from Institutional Ethics committee and taking prior consent, data of all patients who were diagnosed to have Type 2 Diabetes Mellitus fulfilling inclusion criteria during the period of 1st January 2018 to 30th June 2019 attending OPDs in Maharajah's Institute of Medical Sciences, Vizianagaram was collected. Each patient's baseline demographic data age, sex, duration of diabetes was recorded. The interviewed cases were subjected to ultrasound for diagnosis of NAFLD. The patients were divided into two groups based on the presence or absence of fatty Liver. They were further evaluated by measurement of Body Mass Index (BMI), Glycosylated hemoglobin (HbA1c), Lipid profile (FLP), liver function tests (LFTs)

Statistical Analysis

Results were presented as frequency and percentages for Categorical variables and mean+/- SD for continuous variables. Statistical calculations were done using Chi-square tests for categorical data and on independent t-test for continuous data. $P<0.05$ was considered significant. The calculations were carried out using SPSS soft ware (Statistical Package for the Social Sciences).

Results

Our present study, which included 100 patients, was designed to assess the prevalence of Nonalcoholic fatty liver in type 2 diabetic patients who were on OHAs for blood sugar control and insulin naïve.

Table 1: Distribution of Study Subjects According To Age

Age in years	Frequency	Percent
43-50	45	45.0
51-60	40	40.0
61-70	10	10.0
>70	5	5.0
Total	100	100.0

The maximum number of patients were in the age group 43-50 years. Mean age was 53.9 ± 6 years. Males in the study were 51%, and females were 49%. 60% of the patients had a duration of diabetes between 10-20 years, 36% had duration <10 years and 4% > 20yrs

Table 2: USG abdomen of the studied patients

USG Fatty Liver	Frequency	Percent
Yes	62	62
No	38	38
Total	100	100

Prevalence of fatty liver on USG was 62%

Table 3: Comparision of sex distribution in patients with and without NAFLD

Variable	USG Fatty Liver	N	Minimum	Maximum	Mean	SD	P-value
Age in years	Yes	62	43.0	74.0	53.06	6.20	0.11
	No	38	47.0	73.0	55.32	7.72	

The mean age of the NAFLD group was 53.06±6.20, and that of the normal liver group was55.32±7.72 with a (P-value 0.11)

Table 4: Comparision of sex distribution in patients with andwithout NAFLD

Variable	Category	USG Fatty Liver			
		Yes		No	
		n	%	n	%
Sex	Female	34	54.8%	15	39.5%
	Male	28	45.2%	23	60.5%
Total	62		100.0%	38	100.0%
P=0.15					

Table 5: Comparison of BMI in patients with and without NAFLD by USG

BMI					P-value
USG Fatty Liver	Minimum	Maximum	Mean	SD	
Yes	19.72	32.05	27.81	2.54	<0.001
No	17.71	26.67	22.98	2.10	
Total	17.71	32.05	25.98	3.34	

The mean BMI in patients with NAFLD and in the patients with normal liver in the present study was 27.81±2.54 and 22.98±2.10, respectively, with significant P value(P-<0.001*).

Table 6: Comparision of BMI in patients with and without NAFLD

	USG Fatty Liver			
	Yes		No	
BMI (kg/m^2)	n	%	n	%
<18.5	0	0.0%	3	7.9%
18.5-24.9	3	4.8%	31	81.6%
25-29.9	44	71.0%	4	10.5%
≥30	15	24.2%	0	0.0%
Total	62	100.0%	38	100.0%
P<0.001				

The number of patients with a BMI greater than 24.9 kg/m^2 in the NAFLD group is 44, and that of the normal liver group is 4. Correlation showed a significant association of NAFLD withhigh BMI with (P value<0.001)

Table 7: Comparison of glucose metabolism parameters between patients with and without NAFLD

Variable	USG FattyLiver	Minimum	Maximum	Mean	SD	P-value
FBS (mg/dl)	Yes	63.0	250.0	147.35	46.32	0.29
	No	21.0	240.0	136.87	51.60	
	Total	21.0	250.0	143.37	48.41	
PPBS(mg/dl)	Yes	104.0	360.0	222.24	68.87	0.19
	No	129.0	340.0	204.34	63.57	
	Total	104.0	360.0	215.44	67.15	
HbA1C	Yes	5.8	13.0	9.17	1.81	0.23
	No	6.2	13.0	8.73	1.75	
	Total	5.8	13.0	9.01	1.79	
Duration of DM -years	Yes	1.0	22.0	10.56	4.48	0.54
	No	3.0	32.0	11.24	6.50	
	Total	1.0	32.0	10.82	5.32	

The mean FBS of the NAFLD group was 147.35±46.32, and that of the normal group was 136±51.60 (P value0.29). The mean PPBS of the NAFLD group was

222.24±68.87, and that of the normal group was 204.34±63.57 (P-value 0.19). The mean HbA1C of NAFLD group was 9.17±1.81, and that of the normal group was 8.73±1.75 (P value0.23). The mean duration of diabetes of the NAFLD group was 10.56±4.48 years, and that of the normal group was 10.56±4.48 years (P-value 0.54)

Table 8: Comparison of lipid profile parameters between patients with and without NAFLD

Variable	USG FattyLiver	Minimum	Maximum	Mean	SD	P-value
	Yes	20.0	55.0	36.60	8.27	
	No	22.0	60.0	41.71	8.39	
HDL(mg/dl)	Total	20.0	60.0	38.54	8.64	0.004
	Yes	25.0	191.0	109.66	37.41	
	No	45.0	180.0	101.68	38.23	
LDL(mg/dl)	Total	25.0	191.0	106.63	37.73	0.31
	Yes	59.0	433.0	170.60	73.36	
	No	45.0	301.0	129.11	54.27	
TG(mg/dl)	Total	45.0	433.0	154.83	69.47	0.003
	Yes	89.0	300.0	186.11	43.10	
	No	105.0	230.0	173.87	33.71	
TC(mg/dl)	Total	89.0	300.0	181.46	40.06	0.14

The mean HDL levels of the subjects with NAFLD were 36.30±8.27, whereas, in the normal study group, it was 41.71±8.39. The difference was statistically significant (p- value 0.004). The Mean TRIGLYCERIDE levels of patients with NAFLD were 170.60±73.36, and that of the normal liver group was 129.11±54.27. The difference was statistically significant (P-value 0.003)

Table 9 : Comparison of liver enzyme parameters between patients with and without NAFLD

Variable	USG FattyLiver	Minimum	Maximum	Mean	SD	P-value
	Yes	15.0	99.0	43.00	21.85	
	No	11.0	56.0	34.68	14.61	
SGOT (IU/L)	Total	11.0	99.0	39.84	19.76	0.04
	Yes	15.0	99.0	42.39	19.75	
	No	9.0	63.0	34.03	17.35	
SGPT(IU/L)	Total	9.0	99.0	39.21	19.22	0.03
	Yes	18.0	368.0	123.79	62.81	
	No	41.0	356.0	124.11	66.06	
ALP(IU/L)	Total	18.0	368.0	123.91	63.73	0.98

The difference in mean SGOT and SGPT in the NAFLD group and that of the normal group was statistically significant

Discussion

Our present study, which included 100 patients, was designed to assess the prevalence of Nonalcoholic fatty liver in type 2 diabetic patients who were on OHAs for blood sugar control and insulin naïve.
The prevalence, as assessed by ultrasound examination, was found 67% in the present study. In the study by AK Agarwal et al[9] 71(57.2%) patients had evidence of fatty liver on ultrasound. In study by Somalwar et al[10] prevalence was 56.66%

The mean age of subjects in the NAFLD group was 53.92 ± 6.87years. The majority of all subjects studied were in the age group of 43-50 years. Few studies have shown that the prevalence of NAFLD increases with age. Somalwar et al[10] the mean age NAFLD was 55.73 ± 6.08years ,with out fatty liver 54.51 ± 5.46 years statistically insignificant, Targher et al[11] mean age NAFLD was 65 ± 6,with out fatty liver 60 ± 4 statistically significant(P-value 0.001)

The study revealed that the prevalence of NAFLD in male T2DM patients was 45.2%, whereas in females it was 54.8%. The difference in prevalence among males and females was found to be statistically insignificant (P value 0.15). This finding was comparable to that of Merat et al [12], Somalwar et al[10].

It is known that NAFLD is associated with metabolic syndrome. As shown in many studies, the present study also demonstrated high BMI, has an association with NAFLD. The mean BMI in patients with NAFLD and in patients with normal liver in the present study was 27.81±2.54(kg/m^2) and 22.98 ± 10(kg/m^2), respectively. The difference was statistically significant.. The results are in concordance with numerous other studies including Shobha et al[13], Somalwar et al[10], Merat et al[12] Sheela et al[14] and Targher et al[11], which showed anassociation between and high BMI and NAFLD.

Present study showed increased triglyceride levels (mean 170.60 ± 73.36mg/dl) in the diabetic fatty liver group as compared to non-fatty liver group (triglycerides mean 41.71 ±8.39 mg/dl), and the results were statistically significant (P-value 0.004).

In a multiple logistic regression analysis by Shobha et al[13], high triglycerides were also found to be an independent predictor of fatty liver in the diabetic population. In the study by Merat el al[12], among lipid parameters, only the mean triglyceride levels showed a significant correlation with the presence of NAFLD (p=0.036).

The mean HDL levels in the diabetic fatty liver group and the normal liver group were 36.30 ±8.27 mg/dl and 41.71 ± 8.39 mg/dl, respectively. The difference was statistically significant. (P value 0.004). Study findings are consistent with numerous other studies which showed similar results. In the studyby Somalwar et al[10], subjects with NAFLD (37.05 ± 5.74 mg/dl) had a significantly lower mean levelsof HDL than the normal study group(45.56 ± 5.68 mg/dl).

The mean total cholesterol levels of the subjects with NAFLD was 186.11 ± 43.10 mg/dl, Whereas in the normal liver study group, it was 173.87 ±33.71 mg/dl.

There was no statistically significant difference in the means of both the study groups. (P-value 0.14). Merat et al[12] mean total cholesterol levels of the subjects with NAFLD was 224.7 ± 59.8 mg/dl, Whereas in the normal liver study group, it was 212 ± 49.5 mg/dl.There was no statistically significant difference. Somalwar et al[10]., showed higher mean cholesterol values in the NAFLD group(255.23 ± 31.80 mg/dl) than the normal liver group(173.27 ± 36.73 mg/dl) and is statistically significant

The study results with respect to LDL levels ,subjects with NAFLD was 100.3 ± 35.3 mg/dl, Whereas in the normal liver study group, it was 98.3 ± 36.4 mg/dl were comparable with that of studies by Merat et al [12], Somalwar et al [10], Shahbazian et al[15] which was not stasistically significant .

Patients with type-II diabetes mellitus have resistance to peripheral action of insulin. This insulin deficiency, by promoting lipolysis, is an important cause of fatty liver in patients with poorly controlled diabetes mellitus. The difference between all the glucose parameters of the diabetic NAFLD and the normal liver group was not statistically significant. These results were in accordance with other studies done by Merat et al[12], Shahbazian et al [15], Agarwal, et al[9].

The mean AST in the diabetic NAFLD group was 43.00 ± 21.85 IU/L, and the normal liver group was 34.68 ± 14.61 IU/L. The difference was statistically significant. (P value 0.04). The mean ALT in the diabetic NAFLD group was 42.39 ± 19.75 IU/L, and in the normal liver group was 34.03 ± 17.35 IU/L. The difference was statistically significant. (P value 0.03). In the study by Shobha et al [13], the mean AST and ALT levels were 37.23 ± 17.9 IU/L and 51.92 ± 27.3 IU/L, respectively in NAFLD population the difference was statistically significant.

Conclusion

The prevalence of NAFLD is high among diabetic patients it should be screened early and treated. High BMI is associated with NAFLD. Increased triglyceride levels and low HDLseen.in patients with diabetic fatty liver. No significant difference in the mean LDL and total cholesterol between groups. There was no statistically significant difference in FBS, PPBS, HbA1C levels between the two groups.

Limitation

Ultrasound was used to identify NAFLD. It has a sensitivity of 60%-94% and a specificity of 66%-95% for detecting steatosis. Its main limitation is that it is operator-dependent and cannot detect mild steatosis (5%-30%)

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