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Original Research Article

Prevalence of non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes mellitus and its correlation with coronary artery disease (CAD)

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ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) is a common association of Type 2 diabetes mellitus and diabetes mellitus is a leading risk factor for coronary artery disease (CAD). This study aims at estimating the prevalence of NAFLD by ultrasonography and to correlate NAFLD with CAD in a group of patients with Type 2 DM.
Methods: Consecutive patients of Type 2 diabetes fulfilling the inclusion criteria were recruited. Clinical and biochemical parameters were recorded. NAFLD was diagnosed by ultrasonography.
Results: The prevalence of NAFLD was 41.2% in the study group (n=114) and was higher in females. Prevalence of NAFLD in the younger age group was significantly higher than that in the older age group. Elevated liver enzymes, elevated HbA1C, duration of diabetes, obesity, acanthosis nigricans and metabolic syndrome were all significantly associated with NAFLD. CAD was significantly higher in the NAFLD subgroup (72.46%) compared to the non-NAFLD subgroup (52.63%) (p=0.001). Using binary logistic regression analysis, it was found that NAFLD is an independent predictor of CAD (p=0.002).
Conclusions: NAFLD is extremely common in people with Type 2 diabetes and is associated with a higher prevalence of CAD.NAFLD is an independent risk factor for development of CAD. Thus, identification of NAFLD in diabetics might help in predicting the risk of CAD and to adopt the necessary preventive strategy.

Keywords: Coronary artery disease, Diabetes mellitus, Non-alcoholic fatty liver disease

INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) is one of the epidemics of our generation, being the leading cause of liver dysfunction worldwide and a rapidly growing health problem. Non-Alcoholic Fatty Liver Disease(NAFLD) is a condition defined by excessive fat accumulation in the form of triglycerides (steatosis) in the liver (>5% of hepatocytes histologically). The pathological picture bears a striking resemblance to that of alcohol-induced liver injury, but it occurs in individuals who deny a significant history of alcohol ingestion.[1] The spectrum of NAFLD ranges from simple steatosis to steatohepatitis (NASH), cirrhosis and hepatocellular carcinoma (HCC), in the absence of excessive alcohol intake.[2] NAFLD is strongly associated with diseases of affluence such as obesity, Type 2 diabetes mellitus (T2DM) or insulin resistance, hypertension, and dyslipidemia. It has been regarded as the liver manifestation of the metabolic syndrome.[3] This multi-faceted condition affects 20-33% of the general population. The overall prevalence of NAFLD in western countries varies from 15-40% and in Asian countries from 9-40%.[4,5] As the pathogenesis of the condition is closely linked to insulin resistance (IR), its

prevalence parallels that of increasing rates of obesity and type 2 diabetes worldwide. It has been estimated that 70-75% of type 2 diabetic patients may have some form of NAFLD.[6]

India is evolving into the diabetic capital of the world and NAFLD is emerging as an important cause of liver disease. Even physically lean Indians may be metabolically obese. Epidemiological studies suggest the prevalence of NAFLD to be around 9-32% in general Indian population. The real prevalence is unknown since NAFLD is often undiagnosed and most subjects with NAFLD, even those with diabetes, have normal liver aminotransferases and clinicians do not suspect the potential presence of NAFLD.

The prevalence of NAFLD has doubled during last 20 years, whereas the prevalence of other chronic liver diseases has remained stable or even decreased. The current epidemics of diabetes and obesity in both developed and developing countries suggest that numbers will continue to rise, indicating that NASH will become an increasingly common liver problem in both rich and poor countries, increasing the global burden of liver disease.

If NAFLD is associated with T2DM and metabolic syndrome both of which are established risk factors for cardio vascular disease (CVD) one might expect that elevations in liver enzymes and liver fat may signal increased CVD risk. This is supported by recent data which suggest that the presence of NAFLD in type 2 diabetes may also be linked to increased cardiovascular disease risk independently of components of the metabolic syndrome.[7]

But this has to be verified by larger studies. If NAFLD is proven to be linked with CVD risk, the identification of NAFLD in type 2 diabetes may help in predicting CVD risk and this sub-group of diabetic patients can be targeted with more intensive therapy to decrease their risk of future CVD events.[8-10] However, the evidence has been inconsistent in this regard.

In this scenario, it would be appropriate to estimate the prevalence of NAFLD in Type 2 Diabetes mellitus and its correlation with coronary artery disease and cardiovascular risk factors. Aim of the study is to estimate the prevalence of NAFLD in patients with Type 2 DM admitted in the medical wards of Government T. D. Medical College Alappuzha, a tertiary care teaching hospital in Kerala, South India and to study and compare the prevalence of symptomatic/manifest CAD in diabetics with and without NAFLD.

METHODS

The study was done in wards of Dept. of General Medicine, Government T. D. Medical College, Alappuzha, Kerala. It was a descriptive (cross-sectional) study done during August 2014 to July 2015. Both male and female patients more than 40 years with type 2 diabetes were included in the study. Patients with daily alcohol consumption of >20g or with evidence of acute or chronic viral hepatitis or liver disease due to any other cause were excluded from the study. Patients who were on hepatotoxic medications were also excluded. All consecutive adult patients with Type 2 DM fulfilling the inclusion criteria admitted to the medical wards of the institution during the study period were selected after getting informed consent.

On admission, the following data was collected from each patient which included, name, age, sex, present illness, co-morbidities, weight, height, BMI, waist-hip ratio. Examination of patient also included general examination and system examination along with recording of vitals.

Hematological parameters including haemoglobin, total leukocyte count, differential leukocyte count, platelet count, ESR and metabolic parameters like fasting blood sugar, postprandial blood sugar, glycated haemoglobin, liver function test, renal function test routine urine examination including microscopy, ultrasonogram of abdomen and an ECG were monitored. Cardiac Troponin I and Echocardiography were done if required.

Definitions in study

NAFLD-diagnostic criteria

- Alcohol consumption <20g/d,
- USG Abdomen suggestive of fatty liver.

Diagnostic criteria of diabetes mellitus (ADA guidelines 2011)

- Symptoms of diabetes plus RBS >or equal to 200 mg/dl or,
- Fasting Plasma Glucose > or equal to 126 or,
- Two-hour Plasma Glucose > 200 after a 75g glucose load,
- HbA1c > 6.5%.

Coronary risk factors

- Obesity: BMI> 30 Waist hip ratio > or equal to 1.0 in male and 0.9 in female,
- Hypertension: Systolic BP >130 or Diastolic BP > 85 or on medication,
- Dyslipidemia: S.TG > 150 mg/dl, S.LDL >100 mg/dl, S. Total Cholesterol>200 mg/dl, S.HDL <40 mg/dl in female, <50 mg/dl in male or taking medication for dyslipidemia.

Symptomatic coronary artery disease (CAD)

- History/Medical Records suggestive of CAD,
- ECG showing ischemic changes,

- Positive Cardiac enzyme marker,
- Echocardiographic findings suggestive of CAD.

Statistical analysis

Data are means +/- SD or proportions. It was analysed using SPSS version 16. Continuous data variables were tested for statistical significance by using the Student's 't' test and Mann-Whitney test. Qualitative variables were tested using Chi-square test. Independent association was predicted using binomial logistic regression analysis and p values < 0.05 were considered significant.

RESULTS

A total of 114 patients with Type 2 DM admitted in the general medicine wards of Department of Medicine, Govt. T.D Medical College, Alappuzha were included in the study. Out of the 114, 60 were males and 54 were females (Figure 1) Most of the patients belonged to the age group 55-70 years.

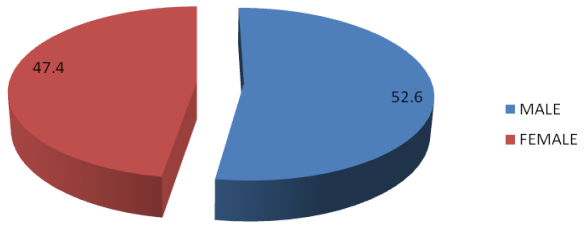

Figure 1: Sex distribution.

Minimum age was 41years and maximum age was 71 years. Mean age was 57.84+/-6.71 years (Figure 2).

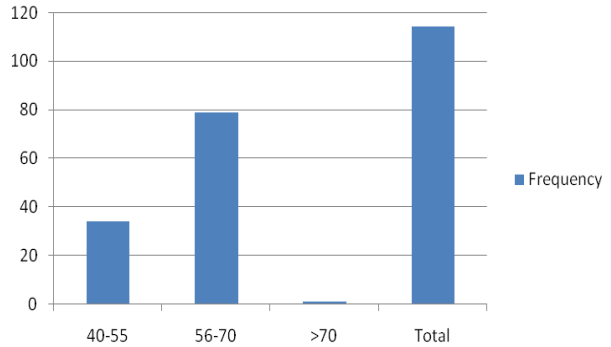

Figure 2: Age distribution.

Majority of the patients had T2DM for 5 to 10 years duration (Figure 3).

63% had family history of diabetes mellitus. 57 of the 114 patients were smokers all of whom were males. 40 out of 114 (35.1%) patients had normal BMI. Majority (n=66) were overweight and 8 were obese (Figure 4).

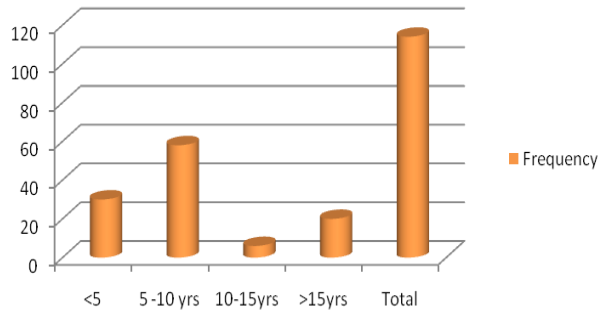

Figure 3: Duration of DM.

Waist hip ratio was elevated in 39 patients (35.4%). On examination, 78 patients had acanthosis nigricans. Out of 78 patients with acanthosis, 41 had NAFLD with significant p value (Figure 5 and 6).

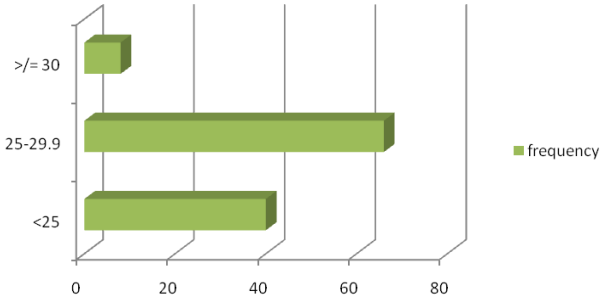

Figure 4: Frequency distribution of BMI.

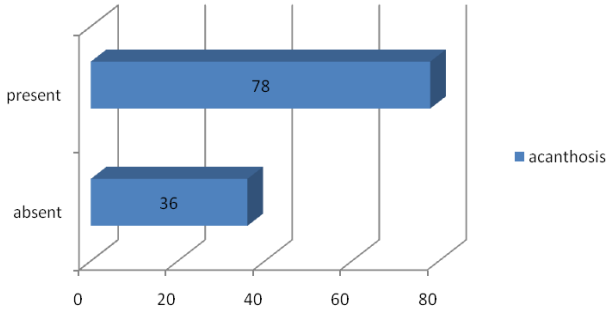

Figure 5: Prevalence of acanthosis nigricans.

Table 1: Frequency of hypertension.

Hypertension	Frequency	Percentage
Absent	54	47.4
Present	60	52.6
Total	114	100

60 out 0f 114 patients (68.4%) had hypertension, (Table 1) 95 (83.3%) had dyslipidemia. Only 51 had fasting blood sugar <110 mg/dl. Majority had HbA1C values between 7% to 9%. 10 patients (8%) had value above 9%. Of the 114 diabetic patients, 47 (41.2%) had NAFLD by ultrasonography (Figure 7). Out of the 60 males, only 15

(25%) had NAFLD whereas out of 54 females,32 (59%) had NAFLD with significant p value (Table 2).

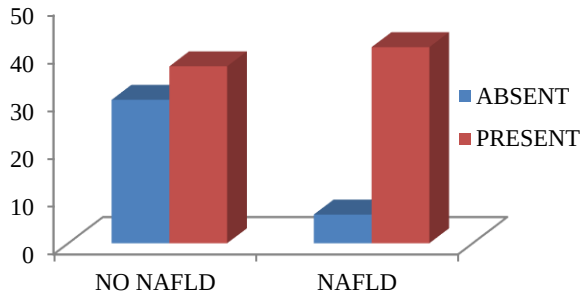

Figure 6: Prevalence of NAFLD in patients with acanthosis nigricanas.

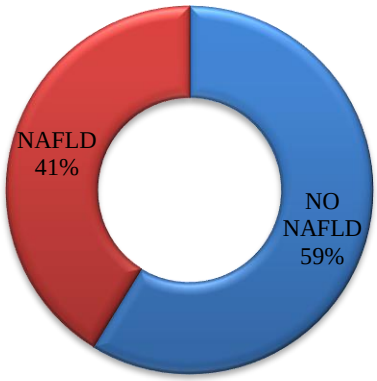

Figure 7: Prevalence of NAFLD in T2DM.

It was observed that the younger age group (40-55 years) had higher proportion of NAFLD with significant p value. But proportion of female sex and metabolic syndrome were also found to be higher in this group (Table 3). Majority in this group were unemployed too.

Table 2: Sex and NAFLD.

		No NAFLD	With NAFLD	Total
Sex	Male	45	15	60
	Female	22	32	54
Total		67	47	114
Chi-square tests		**Value**	**DF**	**P**
Pearson chi-square		13.7668	1	0.000

Table 3: Age group and NAFLD.

		No NAFLD	With NAFLD	Total
Age group	40-55	13	21	34
	56-70	53	26	79
	>70	1	0	1
Total		67	47	114
Chi-square tests		**Value**	**DF**	**P**
Pearson chi-square		8.874577	2	0.012

NAFLD was more prevalent (42.5%) in patients with duration of diabetes>15 yrs. Prevalence in the 0-5 yrs,5-10yrs, and 10-15yrs were 21.27%,23.4% and 12.7% respectively. All patients with DM of duration>10yrs had NAFLD. These observations were statistically significant (Figure 8). 100% of the NAFLD group belonged to the overweight and obese group (p<0.001). Mean Waist hip ratio and BMI were higher in the NAFLD group (0.97+/0.05 and 28.23+/-1.90 respectively) than in the other group (0.95+/-.06 and 25.75+/-2.48) with significant p value (Figure 9). Out of the 47 patients with NAFLD, 43(91%) had dyslipidemia and 30 (63.8%) had hypertension with a significant p value (Table 4).

Table 4: Dyslipideamia and NAFLD.

		No NAFLD	With NAFLD	Total
Dyslipidemia	Absent	15	4	19
	Present	52	43	95
Total		67	47	114
Chi square test		**Value**	**DF**	**P**
Pearson Chi-Square		3.830168	1	0.042

Proportion of NAFLD was higher among patients with HbA1C >9 % (80%). Majority of patients with NAFLD had HbA1C in the range 7.0-8.9% (Table 5). 35 out of the 47 patients (74%) with NAFLD had elevated SGPT and 41 had elevated SGOT (87%) which was statistically significant. Only 45.8% of the patients with NAFLD had clinical hepatomegaly.

This may be due to the higher prevalence of obesity in the NAFLD group. 35 out of 47 patients (72.46%) with NAFLD had CAD, and 30 out of 57 (52.63%) patients without NAFLD had CAD. This difference was statistically significant with a p value of 0.001. A binomial logistic regression was performed to ascertain the effect of NAFLD on the likelihood that participants have CAD (Table 7).

Table 5: HBA1C and NAFLD.

		No NAFLD	With NAFLD	Total
Hba1c	<6.5	7	1	8
	6.5-6.9	11	3	14
	7.0-8.9	47	35	82
	>/=9.0	2	8	10
Total		67	47	114
Chi-square tests		**VALUE**	**DF**	**P**
Pearson chi-square		11.26549	3	0.01

Table 6: CAD and NAFLD.

	No CAD	With CAD	Total
No NAFLD	37	30	67
With NAFLD	12	35	47
Total	49	65	114
Chi square test	**VALUE**	**DF**	**P**
Pearson chi-square	9.936787	1	0.001

The logistic regression model was statistically significant (p value=0.002). Patients with NAFLD were found to be 2.7 times more likely to exhibit CAD than those without NAFLD (Figure 10 and Table 6).

Table 7: Binomial logistic regression analysis.

Variables in the equation							
		B	**S. E.**	**Wald**	**DF**	**Sig.**	**Exp (b)**
Step 1[a]	USG fatty liver (1)	-1.280	0.415	9.513	1	0.002	0.278
	Constant	1.070	0.335	10.239	1	0.001	2.917

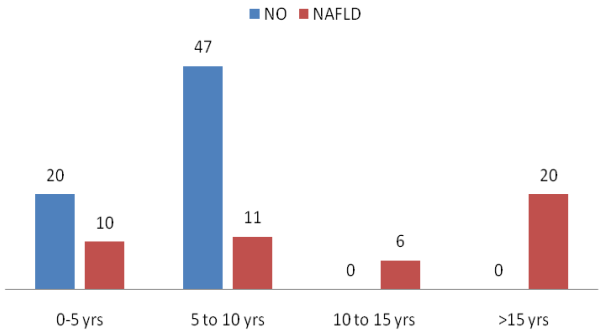

Figure 8: Duration of diabetes and NAFLD.

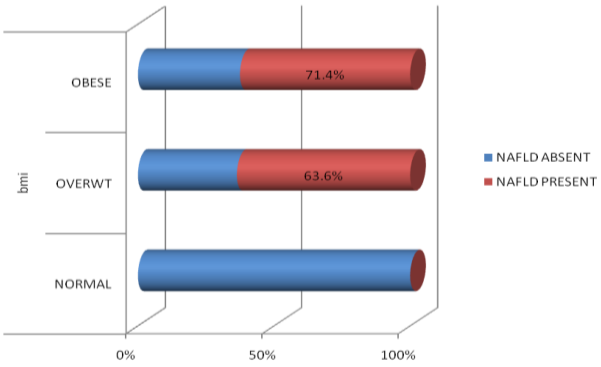

Figure 9: BMI and NAFLD.

DISCUSSION

A number of studies have shown the link between Type 2 DM and NAFLD. Mohan et al observed that the prevalence of NAFLD (54.5%) was significantly higher in patients with diabetes compared to those with pre-diabetes (IGT or IFG) (33%), isolated IGT (32.4%), isolated IFG (27.3%) and normal glucose tolerance (NGT) (22.5%). Also, the prevalence of most cardio-metabolic risk factors was significantly higher in NAFLD patients. In a study by Gupte et al, it was found that mild, moderate, and severe NAFLD was present in 65.5%, 12.5%, and 9.35% of otherwise asymptomatic type 2 diabetics, respectively.[11] Prashanth et al found a high prevalence of NAFLD and NASH in type 2 diabetics which increased with multiple components of the metabolic syndrome.[12] Banerjee et al observed that, on histology, only fatty change was present in 43%, NASH in 40% and more advanced disease in 23%.[13] In the more recent, larger, multicentre study by Kalra et al, prevalence of NAFLD was found to be 56.5%.[14]

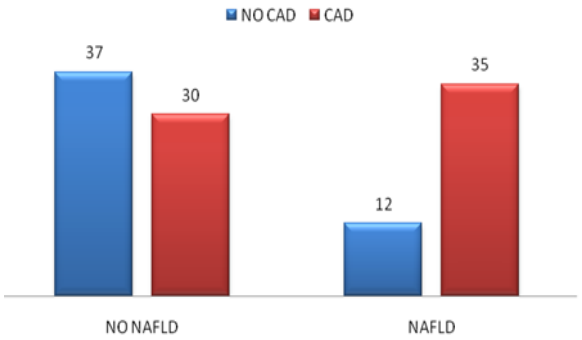

Figure 10: NAFLD and CAD.

In our study, overall prevalence of NAFLD in T2DM was found to be 41%, which is in line with that of Banerjee et al., but lower than the prevalence rate described in other studies.

Most of the studies in India have shown higher prevalence of NAFLD in males than in female population.[15,16] But our study revealed higher prevalence of disease in female (68.1%) than in male (31.9%) population, with same pattern reported in the pan-Indian study by Kalra et al.

Previous studies have also shown that the prevalence of NAFLD increases with age, with most of cases occurring between the age of 40 and 60 years.[17] But in our study, it was observed that the younger age group (40-55 years) had higher within group prevalence of NAFLD (61.8%) compared to older age group (32.9%) with significant p value. This may be due to the facts that the younger age group was dominated by female sex and the metabolic syndrome was commoner in this age group.

Several studies have suggested relationship of NAFLD with features of the Metabolic syndrome. In this study majority of patients in the NAFLD group were overweight/obese (100%), dyslipidemic (91%) or hypertensive (63.8%). So, we can assume that T2DM patients with these co-morbid conditions, definitely have a higher risk of NAFLD.

There was positive correlation between the duration of DM and Glycemic status (Blood sugar and HbA1C levels) and NAFLD. Mean total cholesterol and low HDL levels did not correlate with NAFLD; there was a significant correlation with high triglyceride and high LDL levels All these observations are similar to those in studies by Targher et al., Kalra et al., and Agarwal et a al.[18]

Elevation of levels of ALT and AST or both to mild and moderate levels is a very common finding in NAFLD.[19] Similarly, in T2DM patients, chronic mild elevations of liver enzymes are often encountered emphasizing that T2DM has a strong association with NAFLD.[20] Hypertransaminasaemia in a diabetic, if viral or other causes of liver disease have been excluded, can be sometimes used as a surrogate marker for NAFLD.[21] In our study too, mean SGOT and SGPT levels were found to be higher in the NAFLD. But Targher et al. reported that most patients with NAFLD (63%) had normal transaminase levels making it appear to be insensitive markers for NAFLD.

Acanthosis nigricans (AN) showed a significant association with NAFLD in our study. Niriella et al. reported that AN is significantly more common in NAFLD than normal individuals. But, although AN has a high specificity, it is not a useful test to screen for NAFLD in the community.[22]

The prevalence of CAD was 74.46 % in diabetics with NAFLD and 52.63% in diabetics without NAFLD. Binary logistic regression analysis revealed that NAFLD was a significant independent predictor of CAD (p=0.002). Targher et al found that NAFLD was associated with an increased risk of future CAD events among type 2 diabetics. Liu et al reported that NAFLD was significantly associated with cardiovascular outcomes independent of conventional risk factors.[23] In the studies by Colak et al., C-IMT was found to be significantly higher in patients with NAFLD group (P< 0.001).[24]

Limitations of the study was that the sample size is small. A larger sample size could have provided a greater statistical power and permitted more complete adjustment for potential confounders. Causality in the relation between NAFLD and CVD could not be established, and we could not determine whether the higher CVD prevalence among patients with NAFLD affects long-term mortality. Liver biopsy was not performed to confirm NAFLD. The diagnosis of NAFLD was solely based on ultrasound imaging and exclusion of other causes of chronic liver disease.

CONCLUSION

The prevalence of NAFLD in patients with Type 2 DM was 41%. Prevalence of NAFLD was significantly higher in females. Prevalence of NAFLD in the younger age group was significantly higher than that in the older age group which may be due to the higher prevalence of females and metabolic syndrome in the younger age group. Elevated liver enzymes, elevated HbA1C, duration of diabetes, obesity, acanthosis nigricans were all significantly associated with NAFLD. Coronary artery disease (CAD) was found to be significantly higher among diabetics with NAFLD than in those without NAFLD. NAFLD can be considered as an independent predictor of CAD. Overall, our results suggest that NAFLD is extremely common in people with type 2 diabetes and is associated with a higher prevalence of CAD. NAFLD is an independent risk factor for development of CAD. Thus, identification of NAFLD in diabetics might help in predicting the risk of CAD and to adopt the necessary preventive strategies.

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